Bear

USER/OWNER RESPONSIBILITY

This Bear Medical Systems, Inc. equipment and authorized accessories are designed to function as specified in the relevant instruction manual only when operated, maintained, and repaired in accordance with supplied manuals and instructions. This equipment must be periodically checked, recalibrated, maintained, and components repaired and replaced when necessary for the equipment to operate reliably. Parts that have failed, in whole or in part, exhibit excessive wear, are contaminated, or are otherwise at the end of their useful life should not be used and should be replaced immediately with parts supplied by Bear or parts which are otherwise approved by Bear. Equipment which is not functioning correctly or is otherwise in need of repair or maintenance must not be used until all necessary repairs and/or maintenance have been completed and a factory authorized service representative has determined that the equipment is fit and ready for use. This equipment and any of its accessories or component parts should not be modified.

The owner/user of this equipment shall have the sole responsibility and liability for any damage or injury to persons or property (including the equipment itself) resulting from operation not in accordance with the authorized maintenance instructions, from repair by anyone other than a factory authorized service representative, modification of the equipment or accessories, or from the use of components or accessories that have either been damaged or not authorized for use with this equipment by the factory.

WARRANTY

The BEAR® 33 Volume Ventilator is covered under the warranty expressed on the warranty card attached to the unit at time of sale to the end user.

The warranty stated therein (including its limitations) is the only warranty made by Bear and is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability or fitness for a particular purpose. Bear shall not be liable for consequential or incidental damages of any kind.

The Bear® 33 Volume Ventilator is covered by both U.S. and foreign patents as follows: U.S. Patent No. 4,036,221; Canadian Patent No. 996,196; French Patent No. 2,183,015; West German Patent No. 23 21 574; Japanese Patent No. 880,573; Swedish Patent dated March 26, 1981; United Kingdom Patent No. 1,408,242. In addition, patent applications are pending in Denmark and the Netherlands.

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GLOSSARY OF ABBREVIATIONS AND DEFINITIONS

amp	Ampere
AC	Alternating Current
BATT	Battery
BPM	Breaths Per Minute
cm	Centimeter
cmH_2O	Centimeter of Water Pressure
°C	Degrees Centigrade
DC	Direct Current
°F	Degrees Fahrenheit
EtO	Ethylene Oxide
EXT	Eternal
FIO_2	Fractional Concentration of Inspired Oxygen
Hz	Hertz
ID	Internal Diameter
I:E	Inspiratory Time to Expiratory Time Ratio
INT	Internal
INOP	Inoperative
kg	Kilogram
lb	Pound
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LPM	Liters Per Minute
ml	Milliliter
msec, ms	Millisecond
O_2	Oxygen
PRESS	Pressure
PWR	Power
SIMV	Synchronous Intermittent Mandatory Ventilation
Solenoid	Electrically Operated Valve
T	Time
T_I	Inspiratory Time
VAC	Volts Alternating Current
VDC	Volts Direct Current
VENT	Ventilator
V_T	Tidal Volume

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WARNINGS AND CAUTIONS

The BEAR® 33 Volume Ventilator is intended for use by trained personnel under the direction of a qualified physician.

Personnel operating the ventilator MUST become thoroughly familiar with the instruction manual prior to using the BEAR® 33 Volume Ventilator.

Statements in this manual preceded by the following words are of special significance.

WARNING

Means there is a possibility of personal injury to yourself or others.

CAUTION

Means there is a possibility of damage to the instrument or other property.

NOTE

Indicates points of particular interest for more efficient and convenient operation.

It is recommended that the reader take particular notice of the warnings, cautions and notes provided throughout this manual.

The following WARNINGS must be read and understood before using the BEAR® 33 Volume Ventilator:

WARNINGS

- **Trained competent personnel should be in attendance at all times, for the timely detection of alarm conditions and/or problems.**
- **Alternative systems for providing back-up ventilation (i.e., a manual resuscitator) should be available at all times.**
- **Under no circumstances should the BEAR® 33 Volume Ventilator be used in the presence of flammable anesthetics or solvents due to possible explosion hazard.**
- **An audible alarm indicates an abnormal operating condition and should never go unheeded.**
- **If the CIRCUIT BREAKER should trip, do not reset the circuit breaker more than once. Reset by depressing the pop-out button. If the circuit breaker trips again after resetting, the ventilator should be turned off and the unit referred to an authorized service technician.**
- **Electrical Shock Hazard — DO NOT open or remove the BEAR® 33 Volume Ventilator case. Refer all servicing to an authorized service technician.**
- **Batteries represent explosive hazards. Observe all manufacturer's warnings concerning: placement, handling, connection and ventilation of external 12 VDC batteries.**
- **The patient should never be left unattended when the ALARM SILENCE button is depressed to allow timely detection of alarm conditions.**
- **The internal diameter and placement of the proximal airway pressure sensing line is important. To maintain optimum sensitivity, the $^{3}/_{16}$" line must only be placed at the proximal airway connector.**
- **If the VENT INOP alarm activates, it indicates an internal malfunction. Under such circumstances, the ventilator must be removed from the patient and a back-up system immediately provided, and referred to a qualified service technician. The VENT INOP alarm can only be silenced by turning the ventilator OFF or correcting the VENT INOP condition.**

WARNINGS

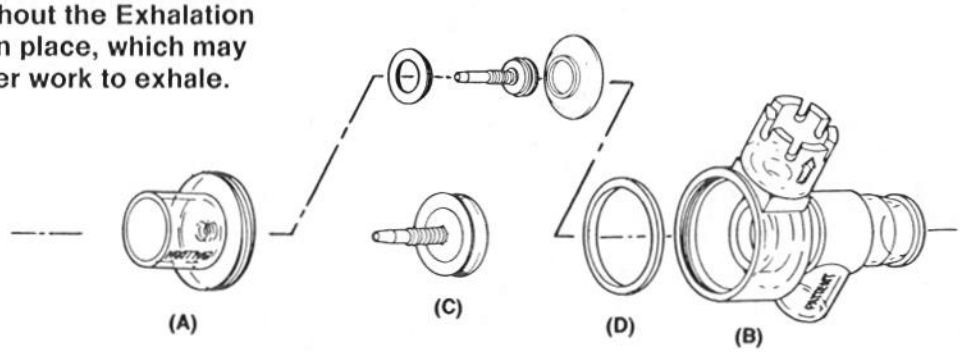
- If the audible ALARM or visual indicator of any ALARM function should fail to activate during an alarm condition or fail to reset after the alarm condition has been cleared and the VISUAL RESET button has been depressed, refer the unit to an authorized service technician.
- A fully charged internal battery provides approximately one hour of ventilator operating time. This battery is a back-up source of power for use during emergencies and transitions between other power source changes. The patient should not be left unattended at any time during use of the internal battery and an alternative power source should be connected immediately.
- When the internal battery is being used and the LO BATT indicator is flashing, it indicates operating time of the ventilator is limited (approximately 15 minutes). The patient should not be left unattended and an alternative power source or means of ventilation MUST be provided immediately.
- The ASSIST SENSITIVITY control must be properly adjusted in the SIMV mode to insure accurate monitoring of spontaneous breaths. It is necessary to properly set the ASSIST SENSITIVITY control in the SIMV mode to synchronize patient effort with ASSISTED and CONTROLLED breaths. Improper adjustment could lead to stacking CONTROLLED breaths on top of the patient's spontaneous breaths (if the sensitivity control is set higher than actual patient effort).
- ASSIST SENSITIVITY must be set below patient baseline pressure in ASSIST CONTROL and SIMV modes to prevent autocycling.
- Always mount the humidifier below the level of the patient and drape the patient circuit so that the condensate does not drain toward the patient. Frequently drain the condensate from the delivery tubes to avoid possible tubing occlusion and discomfort to the patient.
- The optional accumulator used for delivery of oxygen to the patient is *NOT* a calibrated device and requires the use of an O_2 analyzer with alarms in the inspiratory leg of the patient circuit at or near the patient airway. Spontaneous breathing may unfavorably alter the desired FIO_2.
- Do not kink the exhalation balloon drive line or the proximal pressure sensing line. Kinking may result in ventilator malfunction and possible injury.
- Filter patient air of bacteria and particulate matter with a Main Flow Bacteria Filter (Main Flow Bacteria Kit P/N 51000-08104).
- Use only the patient manifold authorized by Bear Medical Systems, Inc. Other manifolds may cause ventilator malfunction or loss of tidal volume.
- Use only exhalation balloons authorized by Bear Medical Systems, Inc. Other balloon assemblies may not seat properly or can be punctured by the strong deflation created by the piston, causing ventilator malfunction.
- Default parameters are not the original parameters set and may not be satisfactory for your patient's condition. Insure adequate ventilation of your patient and take corrective action.

WARNINGS

- Use of PEEP may lead to increased work of breathing in some patients, resulting in rebreathing and CO_2 retention. Evaluate the patient's ability to perform the work of breathing when PEEP is used. The PEEP Valve generates an end expiratory pressure only, and does not maintain CPAP (constant positive airway pressure) during a spontaneous breath.
- Should the ventilator re-enter a default condition, provide an alternative source of ventilation and contact a qualified Service Technician.
- Misplacement of the one-way valve will not allow the patient to exhale. Observe the direction of the arrow, and confirm the ability to exhale.
- Under certain conditions, such as extremely dry weather, static electricity may cause the BEAR® 33 Ventilator to enter the 'Default' program, while operating on battery power. If this occurs, turn the unit off and then back on, and if functioning, reset to the prescribed operating parameters. If 'Default' recurs, remove the unit from service and use an alternative method of ventilation. Reducing the accumulated static charge on yourself by first touching a doorknob or other metal surface will help prevent such occurrences. For futher information, see "DEFAULT PROGRAM", on page 6-14.

WARNINGS

- Do not overtighten the Exhalation Valve Seal assembly. Overtightening may cause seal distortion which could interfere with proper Exhalation Balloon function. Inspect the seal after assembly to ensure proper balloon function.
- Do not use the Patient Manifold without the Exhalation Valve Seal. The balloon assembly will not seat properly without the Exhalation Valve Seal in place, which may cause greater work to exhale.
- During reassembly ensure that the Exhalation Balloon assembly (c) is completely screwed into part (a) so that the two surfaces are flush and tight. If the balloon (c) is not properly seated (to a) excessive exhalation resistance may occur. Inspect the manifold after assembly to ensure that the seal (d) is properly seated and not deformed.



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The following **CAUTIONS** must be read and understood before using the BEAR® 33 Volume Ventilator:

CAUTION

- Do not gas sterilize or steam autoclave the BEAR® 33 Volume Ventilator. The internal components are not compatible with sterilization techniques.
- Do not gas sterilize or steam autoclave PVC tubing with adapters or connectors in place. The PVC tubing will, over time, take the shape of the adapter, causing poor connection and possible leaks.
- A clogged or occluded GAS INLET FILTER or CASE VENT FILTER can cause equipment malfunction. These filters should be inspected daily and cleaned when dust build-up is visible.
- Do not immerse the GAS INLET FILTER or CASE VENT FILTER in liquid sterilizing agents as such agents will cause a decrease in filtration efficiency and an increase in resistance.
- Do not autoclave or ETO sterilize the Patient Manifold with the Exhalation Valve Seal tightly compressed. Deformation of the seal and loss of function may occur.
- Do not operate the ventilator without the GAS INLET FILTER in place. Particulate matter that enters the ventilator could cause damage to the finish of the cylinder wall.
- When the ventilator is not being used, turn the power off. However, leave the unit plugged into the wall. Failure to do this may shorten the life of the internal battery.
- Do not allow condensate to build up in the patient circuit. Condensate entering the machine can impair proper functioning of the ventilator.
- Connect unit to a properly grounded power outlet only.
- Do not use the BEAR® 33 Volume Ventilator or humidifier with a patient until proper operation has been verified.

NOTES

Do not apply excessive force or overtighten the accessory screws during installation of accessories on the bottom of the BEAR® 33 Volume Ventilator.

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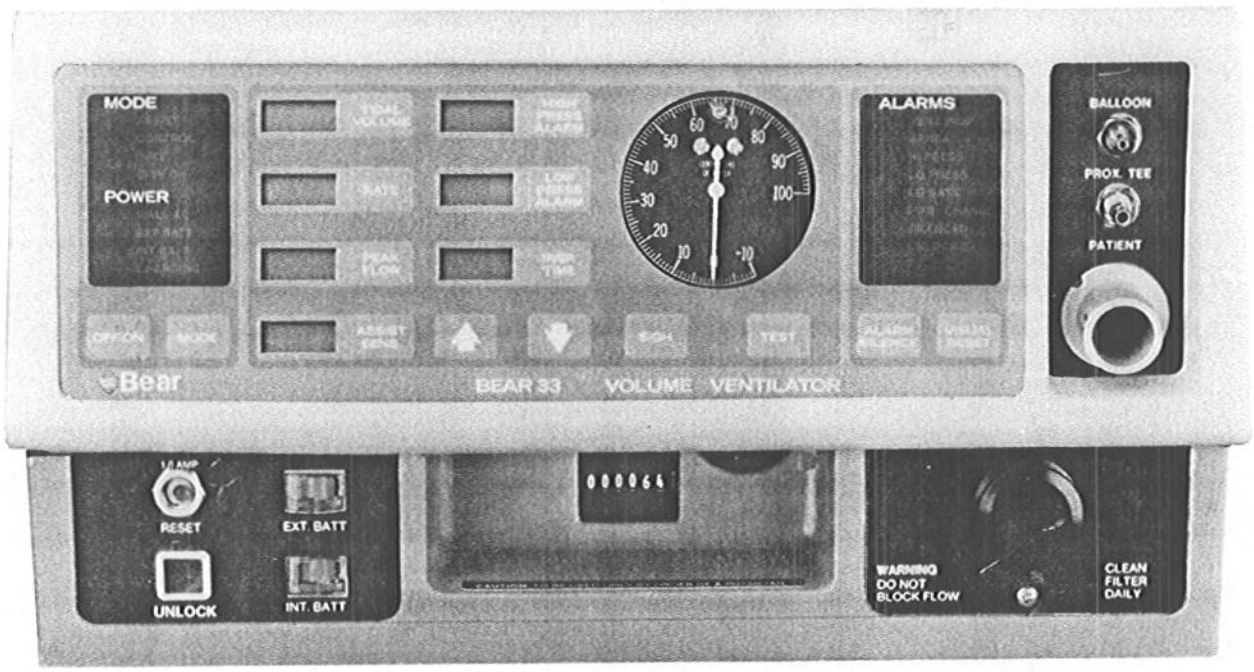


Figure 1

INTRODUCTION

This instruction manual contains installation and operating instructions for the BEAR® 33 Volume Ventilator (Figure 1). It also includes principles of operation, cleaning and sterilizing methods, preventative maintenance and troubleshooting procedures.

DESCRIPTION

The BEAR® 33 Volume Ventilator is a compact, portable device designed to provide volume ventilation for adults and some pediatric patients. The ventilator is designed for long-term use in the home setting, nursing home or hospital. The ventilator provides the following:

- Three (3) modes of ventilation — CONTROL, ASSIST CONTROL and SIMV.
- Predefined operating envelope to prevent I:E Ratios of less than 1:1.
- 100 to 2200 ml tidal volume.
- 2.0 to 40 BPM rate.
- 0.2 to 38L minute volume.
- 10 to 80 cmH_2O peak inspiratory pressure.
- Overpressure Relief Valve cracking pressure of 85 cmH_2O.
- 20 to 120 LPM peak flow.
- 150 to 3300 ml SIGH capability at 6 breaths per hour.
- 0.25 to 4.99 seconds inspiratory time capability.
- Four (4) primary control settings — TIDAL VOLUME, RATE, PEAK FLOW and ASSIST SENSITIVITY.
- Audible/visual alarms for HIGH PRESSURE, LOW PRESSURE, APNEA, POWER SOURCE CHANGED, LOW INTERNAL BATTERY AND VENTILATOR INOPERATIVE conditions.
- Audible COMPLETE POWER FAILURE alarm.
- Digital display of TIDAL VOLUME, RATE, PEAK FLOW, ASSIST SENSITIVITY, HIGH PRESSURE ALARM, LOW PRESSURE ALARM settings and the INSPIRATORY TIME.
- 60 second Alarm Silence with visual alert.

DESCRIPTION

- Visual indicator reset capability.
- Automatic switchover to highest priority power source available.
- Internal battery operation.
- External battery operation.
- Proximal airway pressure monitoring.
- Proximal airway line purge design.
- Panel lock.
- Remote alarm capability (optional).
- Optional oxygen accumulator for increased FIO_2 capability.
- Lightweight portability.
- Environmental Operating Range 32-120°F.

APPLICATION

The portable BEAR® 33 Volume Ventilator is designed for use with long-term patients in the home setting, nursing home or hospital. The ventilator can provide three modes of ventilation with sigh capability to the patient requiring mobility in the home or during transport in a wheelchair, car or airplane.

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

The complete list of performance characteristics and specifications of the BEAR® 33 Volume Ventilator are listed in Tables 1 thru 3.

STANDARD ACCESSORIES

The accessories supplied with the BEAR® 33 Volume Ventilator (50000-00833) are shown in Figures 2-5. The accessories include:

- Patient Circuit Kit with items to assemble a complete patient circuit
- Ventilator inlet filters
- Package of patient training materials
- Clinical instruction manual

The accessories supplied with the BEAR® 33 Volume Ventilator (50000-00834) include only the following:

- Ventilator inlet filters
- Clinical Instruction Manual

OPTIONAL ACCESSORIES

Optional accessories are listed in Figures 6-13. The optional accessories are:

- Main Flow Bacteria Kit
- Adult and Infant Humidifiers
- Remote alarm, 40' and 100' cables
- Oxygen accumulator
- Oxygen accumulator tubing
- Ventilator pole mount
- Humidifier mounting bracket LS420/460 only
- One-way valve
- External battery cables
- External battery cable auto lighter adapter
- PEEP valve
- Universal humidifier bracket

TABLE 1

CONTROL AND DISPLAY PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

CONTROLS	DISPLAYS	DESCRIPTION
OFF/ON		Turns the ventilator on and off. Panel must be unlocked to turn ventilator off.
MODE		Allows the selection of one of three modes: CONTROL, ASSIST CONTROL or SIMV.
PANEL UNLOCK		Unlocks the controls to allow setting ventilator parameters.
TIDAL VOLUME		Allows UP/DOWN buttons to change TIDAL VOLUME from 100 to 2200 cc.
	TIDAL VOLUME	LCD digital displays of the selected TIDAL VOLUME, and ERROR Codes.
RATE		Allows UP/DOWN buttons to change RATE 2.0 to 40 BPM.
	RATE	LCD digital display of the selected RATE.
PEAK FLOW		Allows UP/DOWN buttons to change PEAK FLOW 20 to 120 LPM.
	PEAK FLOW	LCD digital display of the selected PEAK FLOW.
ASSIST SENS		Allows UP/DOWN buttons to change ASSIST SENSITIVITY from -9 to 19 cmH_2O.
	ASSIST SENS	LCD digital display of the proximal pressure at which assist activates.
HIGH PRESS ALARM AND LIMIT		Allows UP/DOWN buttons to change HIGH PRESSURE ALARM setting from 10 to 80 cmH_2O.
	HIGH PRESS ALARM	LCD digital display of the HIGH PRESSURE ALARM setting.
LOW PRESS ALARM		Allows UP/DOWN buttons to change LOW PRESSURE ALARM setting from 3 to 70 cmH_2O.
	LOW PRESS ALARM	LCD digital display of the LOW PRESSURE ALARM setting.
	INSPIRATORY TIME	LCD digital display of the calculated INSPIRATORY TIME from 0.25 to 4.99 seconds.
▲ (UP)		Increases the digital display settings.
▼ (DOWN)		Decreases the digital display settings.
SIGH		Fixed at 1.5 times TIDAL VOLUME within a range of 150 to 3300 ml, 6 sighs/hr.
TEST		Activates the digital display segments, indicators and audible alarm.
ALARM SILENCE		Silences audible alarm for 60 seconds.
VISUAL RESET		Clears visual indication of a corrected alarm condition. Silences POWER CHANGE and LOW BATTERY audible alarm.

TABLE 2

INDICATOR AND DISPLAY PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

OPERATIONAL INDICATORS	COLOR	DESCRIPTION
WALL AC	Green	Indicates WALL AC is powering the ventilator.
EXT BATT	Green	Indicates EXTERNAL BATTERY is powering the ventilator.
INT BATT	Yellow	Indicates INTERNAL BATTERY is powering the ventilator.
CONTROL	Green	Ventilator operating in the CONTROL mode.
ASSIST CONTROL	Green	Ventilator operating in the ASSIST CONTROL mode. The ASSIST portion of this indicator will blink off momentarily when an assisted breath is being delivered.
SIMV	Green	Ventilator operating in the SIMV mode. The ASSIST portion of the ASSIST CONTROL indicator will blink off momentarily when an assisted breath is delivered in SIMV.
SIGH ON	Green	Indicates ventilator is delivering SIGH in the operating mode. This indicator blinks off for the duration of a sigh inspiration.
CHARGING	Green	Indicates internal battery/external battery, if connected, is charging. Indicator is on as long as the unit is plugged into an active AC power source.
Ventilator ON indicator light	Green	Illumination indicates the ventilator is turned ON.
SILENCED	Yellow	Indicates an audible alarm has been silenced for 60 seconds.
UNLOCKED	Yellow	Indicates that the control panel is unlocked.
ALARM INDICATORS	**COLOR**	**DESCRIPTION**
VENT INOP	Red	Indicates a VENTILATOR INOPERATIVE condition exists. See V_T display for error codes.
APNEA	Red	Indicates no breath has occurred within a fixed 20 second period, mechanical or spontaneous.
HI PRESS	Red	Indicates HIGH PRESSURE ALARM setting is violated.
LO PRESS	Red	Indicates LOW PRESSURE ALARM setting is violated.
LO BATT	Red	Less than 25% of internal battery capacity available.
PWR CHANGE	Yellow	Indicates an automatic change to a lower priority power source has occurred.
GAUGE AND METERS	**DESCRIPTION**	
PRESSURE GAUGE	Displays patient proximal airway pressures from -10 to 100 cmH_2O.	
HOUR METER	Displays the number of ventilator operating hours, 0 to 99,999.9 hours.	
INT BATT CHARGE METER	Indicates the status of charge on the internal battery.	
EXT BATT CHARGE METER	Indicates the status of charge on the external battery.	

TABLE 3
PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

AUDIBLE ALARMS	DESCRIPTION
HIGH PRESSURE	Continuous audible alarm and visual indication when peak inspiratory pressure has reached the high pressure setting.
LOW PRESSURE	Continuous audible alarm and visual indication of a low pressure condition.
APNEA	Continuous audible alarm and visual indication when any breath interval has exceeded a fixed 20 second period.
VENTILATOR INOPERATIVE	Continuous audible alarm and visual indication when one of the following ventilator inoperative conditions has occurred: 1) Fail to cycle; 2) High or low inspiratory time; 3) Timing circuit failure; 4) Internal power supply failure or 5) Battery power insufficient to drive the ventilator.
LOW INTERNAL BATTERY	Continuous audible alarm and visual indication when the internal battery has less than 25% operating capacity available.
POWER CHANGE	Continuous audible alarm and visual indication when the ventilator has automatically switched power to a lower priority power source.
COMPLETE POWER FAILURE	Continuous audible alarm when all power sources to the ventilator fail. Alarm duration for a minimum of one (1) minute. No visual indicator.
DEFAULT	Continuous audible alarm (with all LCD's flashing in rotation) to indicate the unit has entered a default condition.
MISCELLANEOUS	**DESCRIPTION**
PRESSURE LIMIT SOLENOID VALVE	Relieves the pressure in the exhalation balloon valve when the HIGH PRESSURE ALARM setting (10 to 80 cmH_2O) is exceeded.
OVERPRESSURE RELIEF VALVE	Opens at 85 cmH_2O. Limits system pressure to a maximum of 125 cmH_2O.
INSPIRATORY GAS FILTRATION	59.0 micron filter.
ALARM LOUDNESS	Fixed at 85 dB_A.
OPERATING NOISE LEVEL	Less than 53 dB_A at 3 feet.
CYLINDER BYPASS CHECK VALVE	Allows the patient to breathe room air provided he can overcome the resistance of the breathing circuit, and reduce PEEP to zero if an optional PEEP value is used.
CIRCUIT BREAKER	Circuit breaker located in AC power line.
REMOTE ALARM OUTPUT JACK	Allows for an optional remote alarm hook-up.
ENVIRONMENTAL OPERATING RANGE	32°F to 120°F.
BATTERY CHARGE CIRCUIT	Charges internal battery at 1.5 A initially, 0.05 A float. Charges external battery at 2 A initially, 0.05 A float.

TABLE 3

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

INLETS	DESCRIPTIONS	
GAS INLET	Allows gas to be drawn into the cylinder. An optional 27 mm barb fitting allows concentrations of 21 to 100% to be drawn into the cylinder from an external reservoir.	
	NOMINAL	**RANGE**
ELECTRICAL INPUTS ALSO AVAILABLE	120 VAC, 60 Hz; 12 VDC	96 TO 132 VAC
	100 VAC, 50-60 Hz; 12 VDC	80 TO 110 VAC
	220 VAC, 50-60 Hz; 12 VDC	176 TO 242 VAC
	240 VAC, 50 Hz; 12 VDC	192 TO 264 VAC

PHYSICAL DIMENSIONS	DESCRIPTION
HEIGHT	7.5 inches (19.2 cm)
WIDTH	14 inches (35.8 cm)
DEPTH	12.8 inches (32.5 cm)
WEIGHT	32 lbs. (14.5 kg)
SHIPPING WEIGHT (includes Standard Accessories)	51 lbs. (23.1 kg)

SECTION 3

BEAR® 33 VOLUME VENTILATOR

OPERATIONAL VERIFICATION PROCEDURE

OPERATIONAL VERIFICATION PROCEDURE (OVP)

The purpose of this procedure is to assist a Qualified Clinician, Hospital Service Technician or Bear Medical Systems Service Technician in establishing a routine verification program which will assist in assuring that the BEAR® 33 Volume Ventilator is in proper operating condition. A checklist is included and should be completed during each operational verification.

A copy of the complete checklist should be kept on file for future reference. The attached checklist may be copied, providing forms for future use.

Familiarity with the function, set-up and operation of the BEAR® 33 Volume Ventilator is assumed (see BEAR® 33 Volume Ventilator Instruction Manual). Perform all tests in the following sequence.

VERIFICATION PROGRAM

Optional Verification should be performed a minimum of once each month.

Certain procedures such as the Oxygen % check, (if applicable), the Display and Alarm Test, and the System Leak Test should be performed at least once every 24 hours that the unit is in clinical use.

Do not use the ventilator unless it passes the Operational Verification Procedure. For servicing, contact a Bear Medical Systems Service Technician, a Bear Medical Systems authorized servicing dealer, or a Bear Medical Systems Trained Hospital Service Technician.

TEST EQUIPMENT REQUIRED

Equipment	Recommended Supplier
Pressure Gauge, 0-150 cmH2O ±1% F/S	Marshalltown Model 86F, with scale in cmH2O, Wallance and Tierman Model FA 14170 or equivalent
Spirometer, water seal	Collins or equivalent
Stopwatch	General purpose
Test Lung	Manley or equivalent
Remote Alarm (if applicable)	Bear Medical Systems P/N 51000-08131
Valve, One-Way	Bear Medical Systems P/N 51000-08118
Mainflow Bacteria Filter	Bear Medical Systems P/N 51000-01054

WARNING

THE FOLLOWING WARNINGS MUST BE READ AND UNDERSTOOD BEFORE PERFORMING ANY OF THE PROCEDURES DESCRIBED IN THIS SECTION.

- UNDER NO CIRCUMSTANCES SHOULD THIS MEDICAL DEVICE BE OPERATED IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR OTHER VOLATILE MATERIALS DUE TO A POSSIBLE EXPLOSION HAZARD.
- LIQUID SPILLED OR DRIPPED INTO THE UNIT MAY CAUSE DAMAGE TO THE UNIT OR RESULT IN AN ELECTRICAL SHOCK HAZARD.
- OXYGEN VIGOROUSLY ACCELERATES COMBUSTION. TO AVOID VIOLENT IGNITION, DO NOT USE ANY GAUGES, VALVES, OR OTHER EQUIPMENT THAT HAS BEEN EXPOSED TO OIL OR GREASE CONTAMINATION.
- DO NOT RELEASE THIS MEDICAL DEVICE IF ANY ALARM/ALERT FUNCTION IS INOPERATIVE. TO DO SO COULD RESULT IN A MALFUNCTION WITHOUT WARNING, POSSIBLY RESULTING IN PERSONAL INJURY, DEATH OR PROPERTY DAMAGE. REFER THE UNIT TO A BEAR MEDICAL SYSTEMS AUTHORIZED SERVICE TECHNICIAN OR A BEAR MEDICAL SYSTEMS TRAINED HOSPITAL SERVICE TECHNICIAN.
- ALL TUBING AND FITTINGS USED TO CONNECT HIGH PRESSURE GAS (AIR AND OXYGEN) FROM THE SOURCE TO THE TEST EQUIPMENT AND FROM THE TEST EQUIPMENT TO THE DEVICE TO BE TESTED MUST BE CAPABLE OF WITHSTANDING 100 PSI (7.03kg/cm²). THE USE OF TUBING AND FITTINGS NOT CAPABLE OF WITHSTANDING THIS PRESSURE COULD CAUSE THE TUBING TO RUPTURE, RESULTING IN PERSONAL INJURY, DEATH OR PROPERTY DAMAGE.
- WHEN VERIFYING THE OPERATION OF THIS MEDICAL DEVICE, DO NOT BREATHE DIRECTLY FROM THE MACHINE. ALWAYS USE A FRESH BACTERIAL FILTER AND TEST CIRCUIT. A HAZARD TO THE HEALTH OF THE SERVICE PERSON MAY RESULT.
- IF ANY OF THE FOLLOWING PROCEDURES CANNOT BE VERIFIED AS OUTLINED IN THIS DOCUMENT, DISCONNECT THIS MEDICAL DEVICE AND REFER IT TO BEAR MEDICAL SYSTEMS OR A BEAR MEDICAL SYSTEMS AUTHORIZED SERVICE FACILITY OR A BEAR MEDICAL SYSTEMS TRAINED HOSPITAL SERVICE TECHNICIAN.

CAUTIONS

The following CAUTIONS must be read and understood before performing any of the procedures described in this section.

- DO NOT USE MEK OR TRICHLOROETHYLENE, AS DAMAGE TO SURFACES MAY RESULT. DO NOT ALLOW ANY LIQUID TO SPILL OR DRIP INTO THE VENTILATOR.
- DO NOT GAS STERILIZE THE VENTILATOR; THE INTERNAL MATERIALS ARE NOT COMPATIBLE WITH GAS STERILIZATION TECHNIQUES.
- BEFORE USING ANY TEST EQUIPMENT (ELECTRONIC OR PNEUMATIC) FOR CALIBRATION PROCEDURES (OTHER THAN OPERATIONAL VERIFICATION), THE ACCURACY OF THE INSTRUMENTS MUST BE CERTIFIED BY A TESTING LABORATORY. THE LABORATORY MASTER TEST INSTRUMENTS MUST BE TRACEABLE TO THE US BUREAU OF STANDARDS OR EQUIVALENT. WHEN VARIANCES EXIST BETWEEN THE INDICATED AND ACTUAL VALUES, THE CALIBRATION CURVES (PROVIDED FOR EACH INSTRUMENT BY THE TESTING LABORATORY) MUST BE USED TO ESTABLISH THE ACTUAL CORRECT VALUES. THIS CERTIFICATION PROCEDURE SHOULD BE PERFORMED AT LEAST ONCE EVERY SIX MONTHS. MORE FREQUENT CERTIFICATION MAY BE REQUIRED BASED ON USAGE AND ENVIRONMENT.

EXTERIOR INSPECTION AND CLEANING

Inspection

Inspect all cords, connectors and fittings. Inspect the housing for cracks or other damage.

Cleaning

1. Before any cleaning of the ventilator, disconnect WALL AC and EXTERNAL BATTERY power sources.
2. Clean the exterior of the ventilator with alcohol. Care should be exercised not to allow any liquid to penetrate the inside of the ventilator.

CAUTION

DO NOT GAS STERILIZE OR STEAM AUTOCLAVE THE VENTILATOR

PATIENT CIRCUIT

1. The entire patient circuit system should be cleaned at least two times per week or following each patient use. All items of the patient circuit, except for the artificial nose or any inline thermometer, should be cleaned with a warm soap and water solution, thoroughly rinsed with warm water and air dried.

The following parts are necessary in the patient circuit system:
Patient Circuit Tubing
Exhalation Valve Tubing
Proximal Pressure Tubing
Proximal Pressure Tee
Flex Tube
Patient Manifold

2. Disassemble and clean the patient manifold in accordance with Section 8, BEAR® 33 Volume Ventilator Clinical Instruction Manual. Inspect:
   - Manifold housing for cracks
   - Exhalation balloon for cuts
   - Exhalation valve seal for damage.

Reassemble manifold with special attention to the Balloon Port Gasket (Figure 3-1A, item 1). Make sure the gasket is seated properly and the Balloon Port Housing (item 2) is lightly hand tightened.

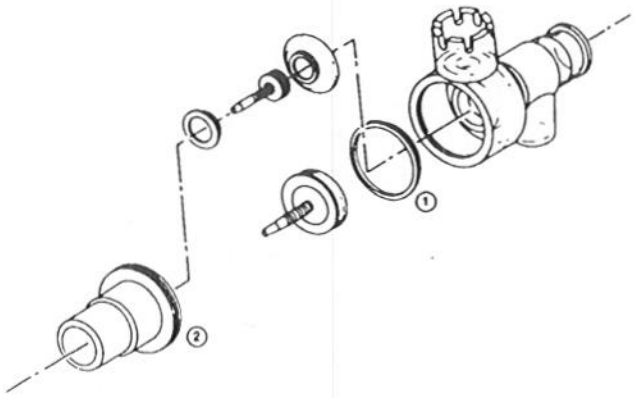


Figure 3-1A
PATIENT MANIFOLD

CAUTION

DO NOT OVERTIGHTEN THE HOUSING.

FILTERS

The Air Inlet and Case inlet filters are easily accessible for removal and cleaning. They may be washed in a warm soap and water solution, thoroughly rised with warm water and air dried.

NOTE

Newer units do not have case inlet filters.

CAUTION

DO NOT OPERATE THE VENTILATOR WITHOUT THE FILTERS IN PLACE.

PLUGS AND CABLES

Plugs and cables may be wiped down with alcohol.

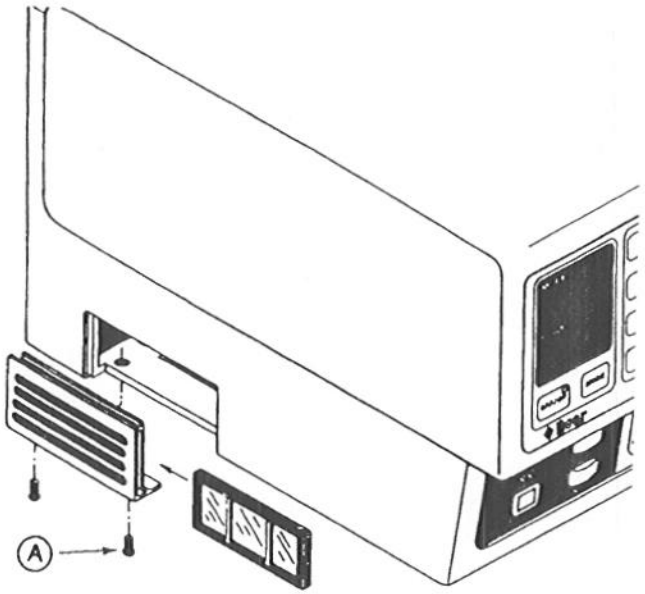


Figure 3-1B
CASE INLET FILTER

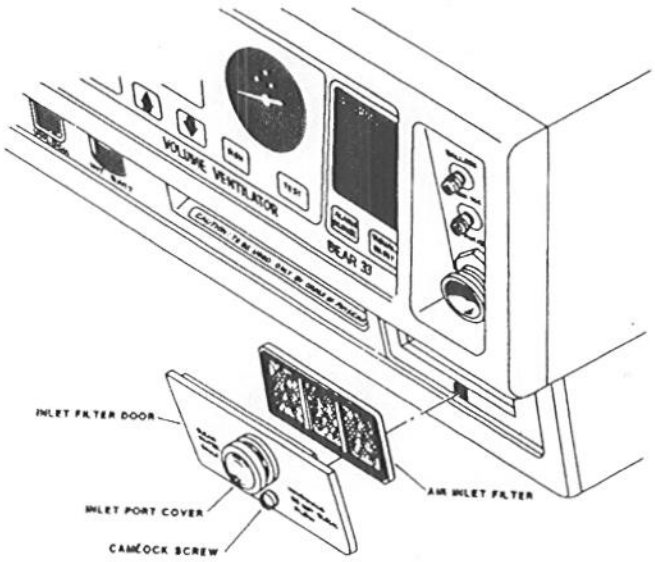


Figure 3-1C
PATIENT AIR INLET FILTER

CASE INLET FILTER (Older units only)

Removal Procedure

1. Remove all tubing connected to the ventilator.
2. Position the ventilator to access and remove the two screws on the left side of the ventilator base (Figure 3-1B).
3. Slide the flush mount filter retainer door away from the ventilator housing.
4. Remove the filter from the slot in the filter retainer door. Clean the filter by washing with water and a mild detergent.

Replacement Procedure

The replacement procedure may be accomplished by reversing the removal procedure.

PATIENT AIR INLET FILTER

Removal Procedure

1. Using an ordinary screwdriver, loosen the screw on the INLET FILTER door (see Figure 3-1C). The screw is captive.
2. Grasp the INLET PORT COVER, pull the door free and set it aside.
3. Remove the AIR INLET FILTER by gently pulling it out of its tight recess. Clean the filter by washing with water and a mild detergent.

Replacement Procedure

After cleaning the filter or substituing a new unit, replacement may be accomplished by reversing the removal procedure.

4

STANDARD SETTINGS FOR OVP

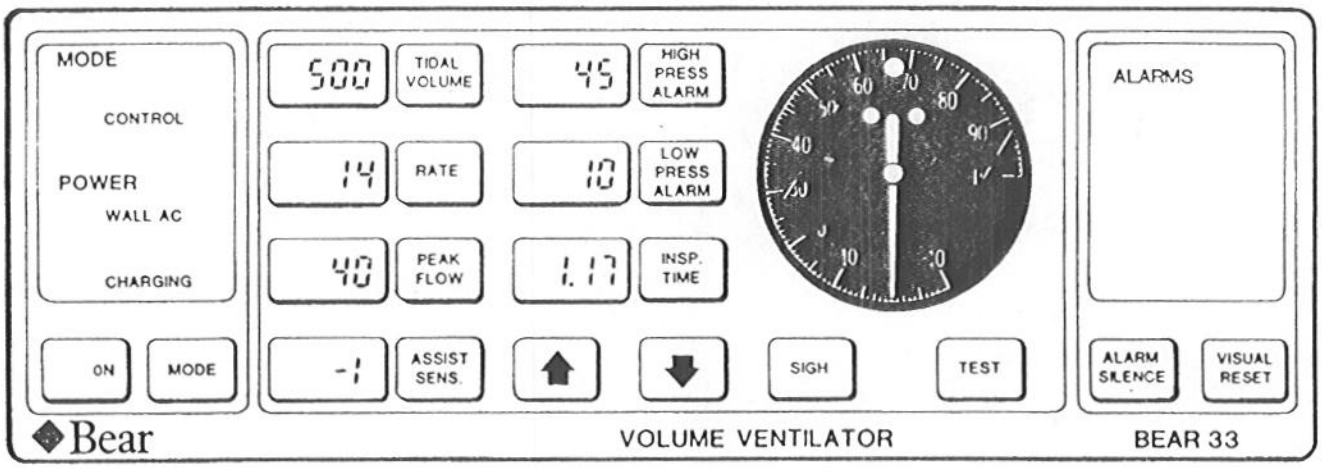


Figure 3-2

SETUP PROCEDURE

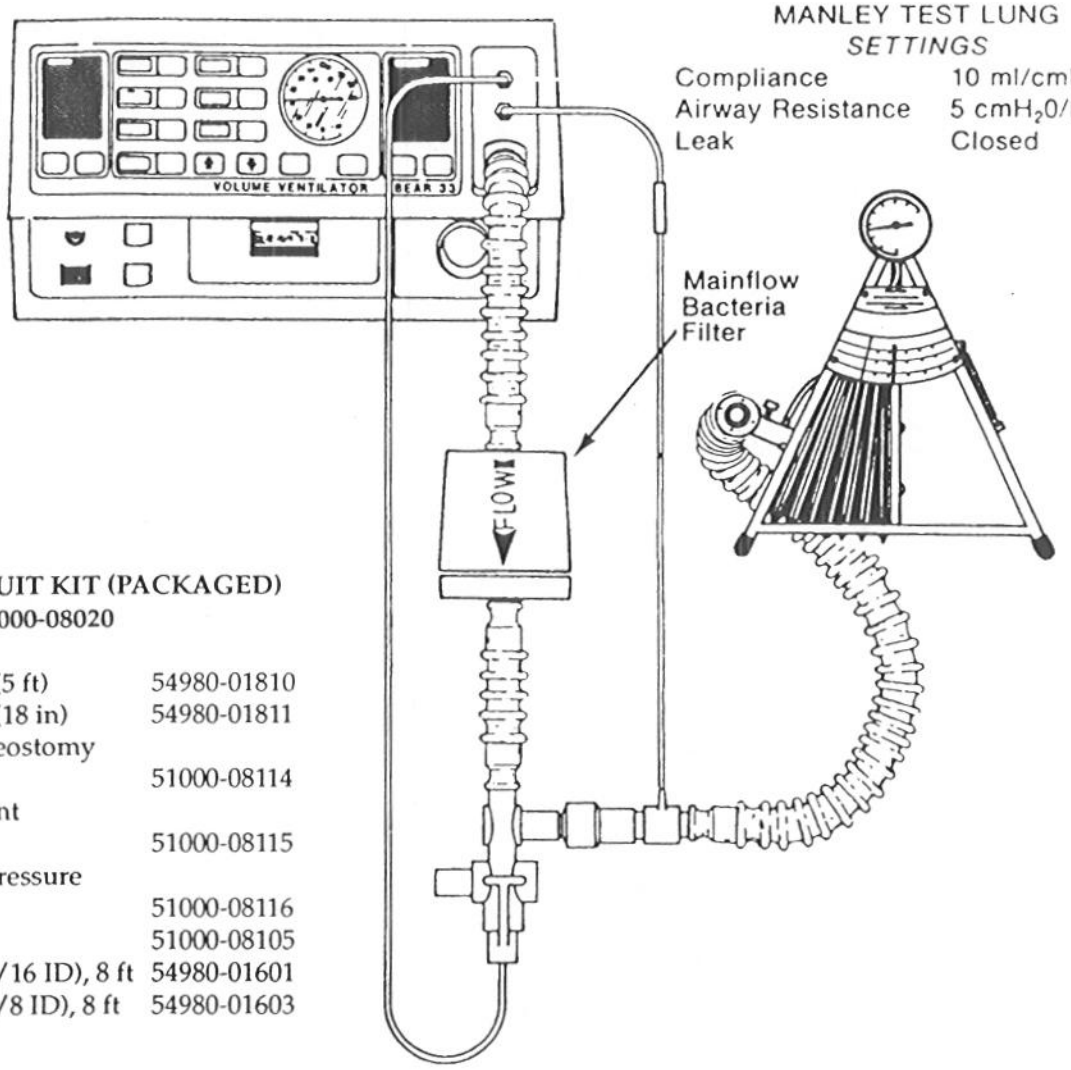
1. Provide an alternate means of ventilation for the patient and disconnect the ventilator to be tested.
2. Connect the STANDARD OVP TEST CIRCUIT as in Figure 3-3. Adjust the Manley Test Lung (if used) for the settings of Compliance, Airway Resistance, and Leak as indicated on Figure 3-3. If an alternate lung is used, make equivalent settings on that device.
3. Connect the ventilator to an active source of AC power. Depress the ON/OFF button to turn the unit ON.

NOTE

The UNLOCK button must be depressed once before changing panel settings or turning the unit off. The panel controls will remain unlocked for 15 seconds after the last panel entry, then they automatically re-lock.

4. UNLOCK the front panel and depress the MODE button as many times as necessary to get a MODE display of CONTROL.
5. Depress the TIDAL VOLUME LCD button and simultaneously depress the UP or DOWN button to change the display. When the display reads 500, release the UP (or DOWN) button, then release the TIDAL VOLUME button.
6. Repeat step 5 for RATE, PEAK FLOW, ASSIST SENS., HIGH PRESS ALARM, and LOW PRESS ALARM. Set each display for the STANDARD SETTING value indicated in Figure 3-2. Verify that the Insp. Time display reads as indicated.

STANDARD OVP TEST CIRCUIT



PATIENT CIRCUIT KIT (PACKAGED)
51000-08020

1.	Patient Tubing (5 ft)	54980-01810
2.	Patient Tubing (18 in)	54980-01811
3.	Flextube, Tracheostomy (Packaged)	51000-08114
4.	Manifold, Patient (Packaged)	51000-08115
5.	Proximal Pressure (Packaged)	51000-08116
6.	Clip, Tubing	51000-08105
7.	Tubing, PVC (3/16 ID), 8 ft	54980-01601
8.	Tubing, PVC (1/8 ID), 8 ft	54980-01603

THIS TEST CIRCUIT WILL BE USED FOR ALL OPERATIONAL VERIFICATION (OVP) TESTS UNLESS OTHERWISE SPECIFIED.

Figure 3-3

DISPLAY READINGS FOR DISPLAY AND ALARM TEST

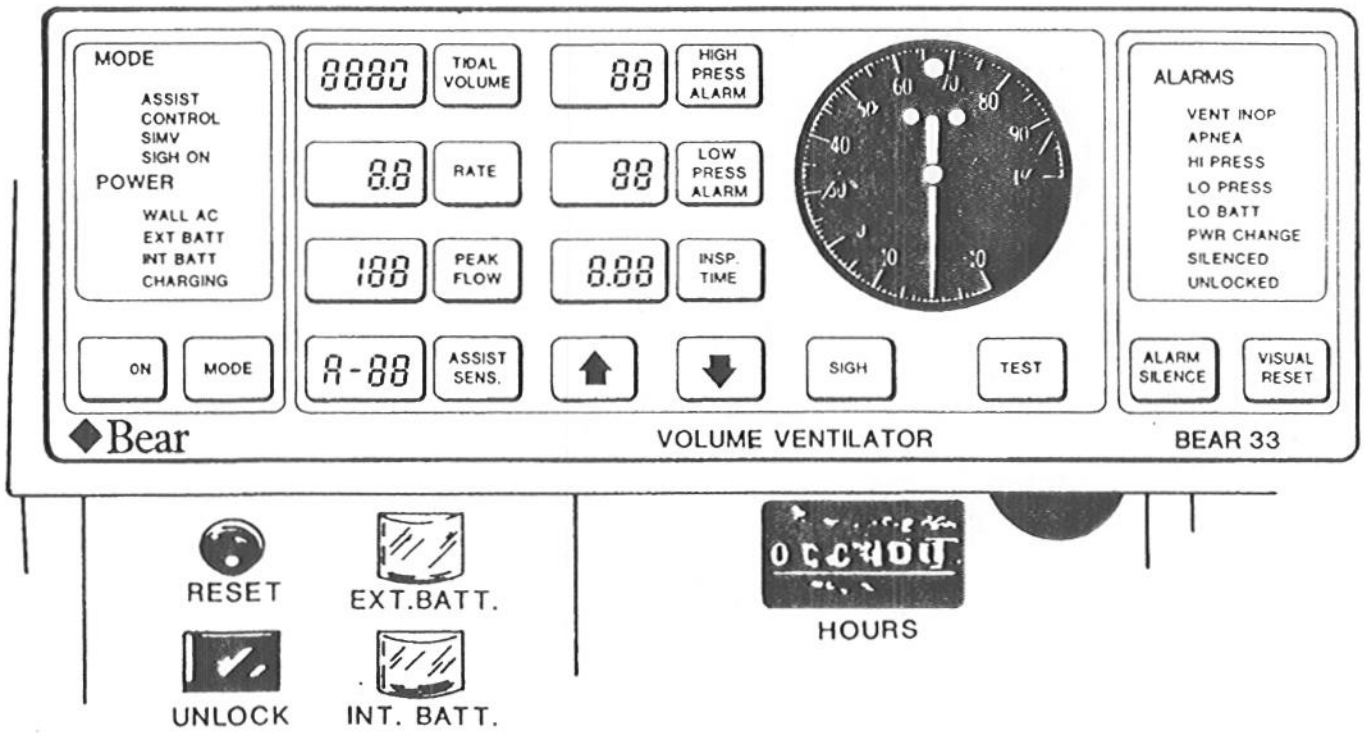


Figure 3-4

DISPLAY AND ALARM TEST

1. Unplug the ventilator from AC power and depress the power ON/OFF button to turn the unit ON. Verify that the INT BATT power display is illuminated and the INT. BATT. meter indicator is in the green area.
2. Wait at least five seconds after power turn on, then depress and hold the TEST button.
3. Carefully examine each LCD display and verify that every individual segment and decimal point illuminates the LCDs as shown in Figure 3-4.
4. Verify that all MODE, POWER and ALARM LED displays are illuminated and the audible alarm is sounding (Figure 3-4).
5. Release the TEST button and connect the REMOTE ALARM (if applicable) by plugging it into the appropriate jack in the back of the ventilator. Again depress the TEST button and verify operation of the REMOTE ALARM.
6. Check the appropriate block on the OVP checklist.

POWER-UP DISPLAY TEST

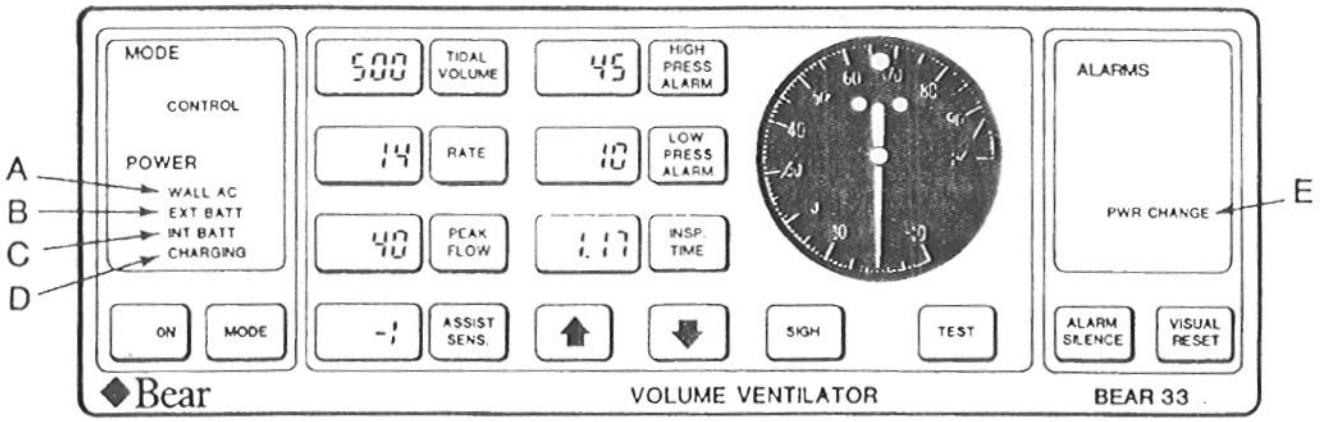


Figure 3-5

POWER-UP TEST

1. Connect the ventilator to an AC power source. Depress the ON/OFF button to turn the ventilator ON. Verify that the WALL AC (Figure 3-5, Item A) and CHARGING LED (Item D) displays are illuminated.
2. Connect the ventilator to an appropriate external 12 VDC power source using External Battery Cable (Bear Medical Systems P/N 51000-08127 or 51000-08129).
3. Disconnect the AC power cord from the AC power source and verify the following:
   a. The WALL AC LED display is OFF and the EXT BATT LED display (Item B) is illuminated.
   b. An audible alarm sounds and the PWR CHANGE ALARM LED display (Item E) is illuminated and flashing.
   c. Depressing the ALARM SILENCE button turns off the audible alarm; a second depression reactivates the audible alarm.
   d. Both the audible alarm and the PWR CHANGE ALARM LED display (Item E) are cancelled by depressing the VISUAL RESET button.
   e. If the external battery source is fully charged, the EXT BATT meter indicator is in the green area of the meter.
4. Disconnect the external battery power source and verify the following:
   a. The EXT BATT LED display (Item B) is OFF and the INT BATT LED display (Item C) is illuminated.
   b. An audible alarm sounds and the PWR CHANGE ALARM LED display (Item E) is illuminated and flashing.
   c. Depressing the ALARM SILENCE button turns off the audible alarm; a second depression reactivates the audible alarm.
   d. Both the audible alarm and the PWR CHANGE ALARM LED display (Item E) are cancelled by depressing the VISUAL RESET button.
   e. The INT BATT meter indicator is in the green area of the meter.
5. Reconnect the AC power cord removed in Step 3 and verify the following:
   a. The INT BATT LED display (Item C) is OFF and the WALL AC LED display (Item A) is illuminated.
   b. Unlock the front panel and depress the ON/OFF button to turn the ventilator OFF. Verify that the CHARGING display (Item D) is illuminated.
6. Check the appropriate block on the OVP checklist.

DISPLAY SETTINGS FOR SYSTEMS LEAK TEST

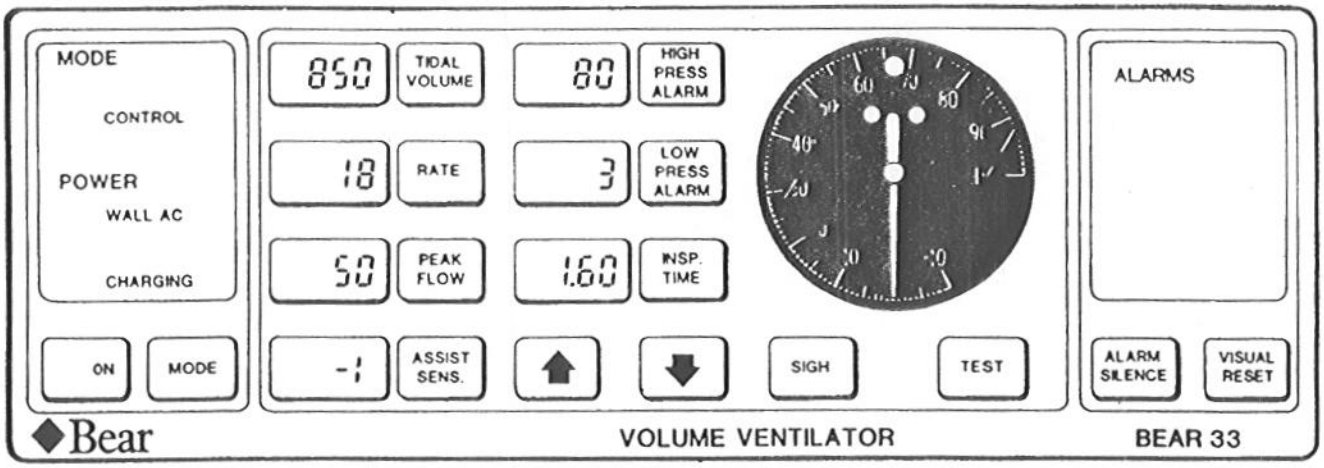


Figure 3-6A

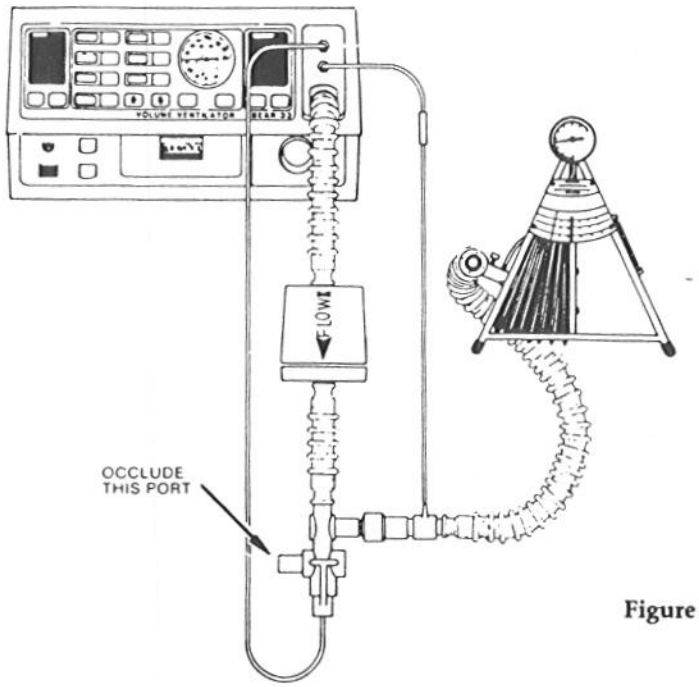


Figure 3-6B

SYSTEM LEAK TEST

1. With the ventilator connected to an AC power source, depress the ON/OFF button to turn the ventilator ON. UNLOCK the panel and set the displays to the values indicated in Figure 3-6A.
2. Observe the PROXIMAL AIRWAY PRESSURE GAUGE. When the gauges reaches peak pressure, occlude the EXHALATION PORT using a check valve or by other means (see Figure 3-6B).
3. Read the peak inspiratory pressure on the PROXIMAL AIRWAY PRESSURE GAUGE and verify that the pressure does not decrease by more than 10 cmH_2O before the next inspiratory cycle starts.

NOTE

Ignore the APNEA alarm and LED display that may occur during this test.

4. If the system fails this test, recheck all patient circuit connections for air seal, hose cracks, cuts, or other leaks. Check that the gasket in the patient manifold is in place and properly seated, then repeat steps 2 and 3.
5. Clear the EXHALATION PORT at the completion of this test.
6. Check the appropriate block on the OVP checklist.

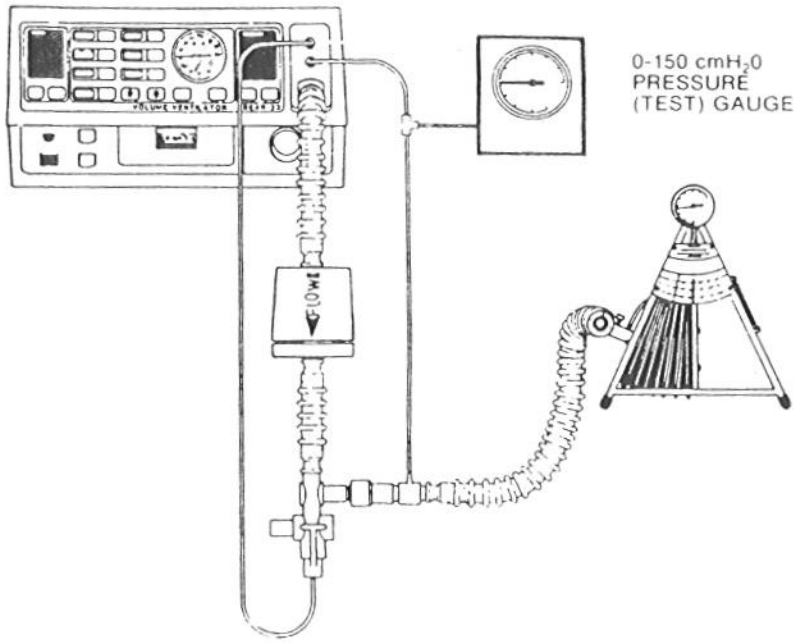


Figure 3-6C

7. Set the Manley Tet Lung with 3 springs, R=200.
8. Connect a 0-150 cmH2O Pressure Test gauge into the PROXIMAL PRESSURE SENSING LINE as indicated in Figure 3-6C.
9. Set the following parameters:
   Tidal Volume – 500 ml
   Breath Rate –5 BPM
   Peak Flow – 20 LPM
   High Pressure Alarm – 80 cmH2O
   Low Pressure Alarm – 10 cmH2O
   Sigh – Off
10. Observe the baseline pressure for 10 breaths using the 0-150 cmH2O gauge. Baseline pressure may not be higher than 1.0 cmH2O.
11. Check the appropriate block on the OVP checklist.

DISPLAY SETTINGS FOR CONTROL MODE TEST

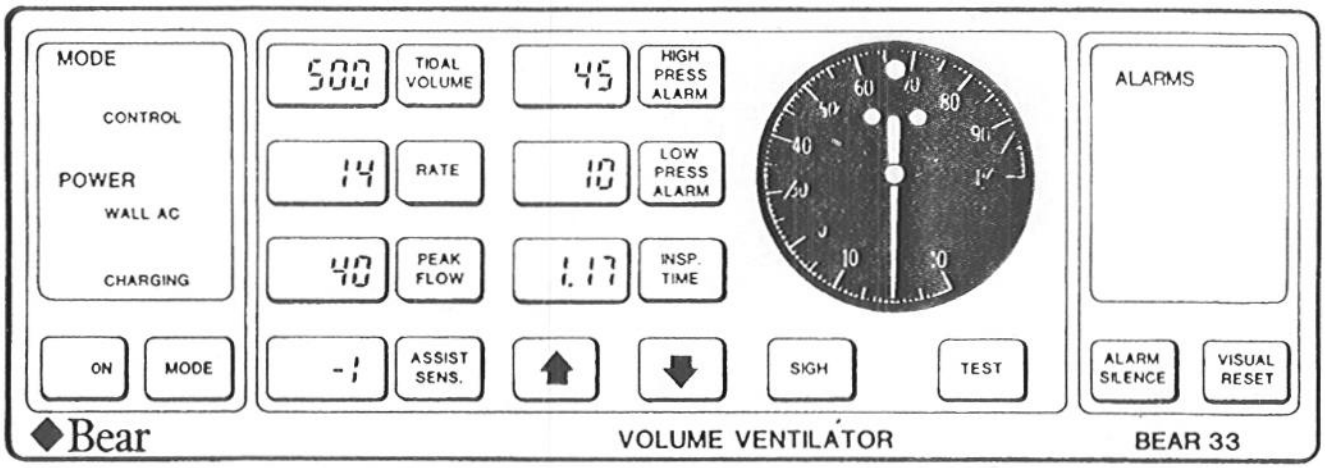


Figure 3-7A

CONTROL MODE TEST

1. UNLOCK the front panel and set the displays to the STANDARD SETTINGS as in Figure 7A. Allow the ventilator to cycle at least twice to stabilize all functions.
2. Visually verify that the test lung is expanding with each breath delivered and contracting during the exhalation phase.
3. Verify that spontaneous breaths may be drawn by pulling or expanding the test lung (Figure 7B) between breaths. Note that the PROXIMAL AIRWAY PRESSURE GAUGE may deflect briefly in the negative direction when a negative pressure is created by expanding the test lung.
4. Verify that an "A" does appear in the ASSIST SENS. LCD display when the test lung is expanded, but an assisted breath does not occur.
5. Check the appropriate block on the OVP checklist.

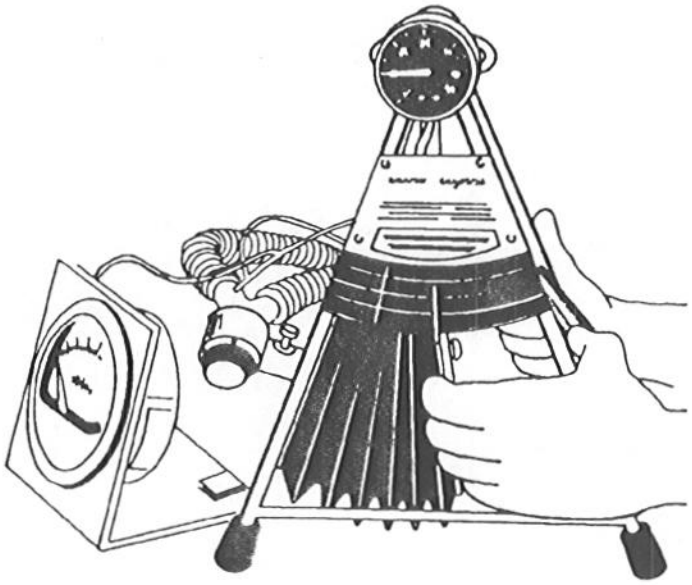


Figure 3-7B

DISPLAY SETTINGS FOR ASSIST CONTROL MODE TEST

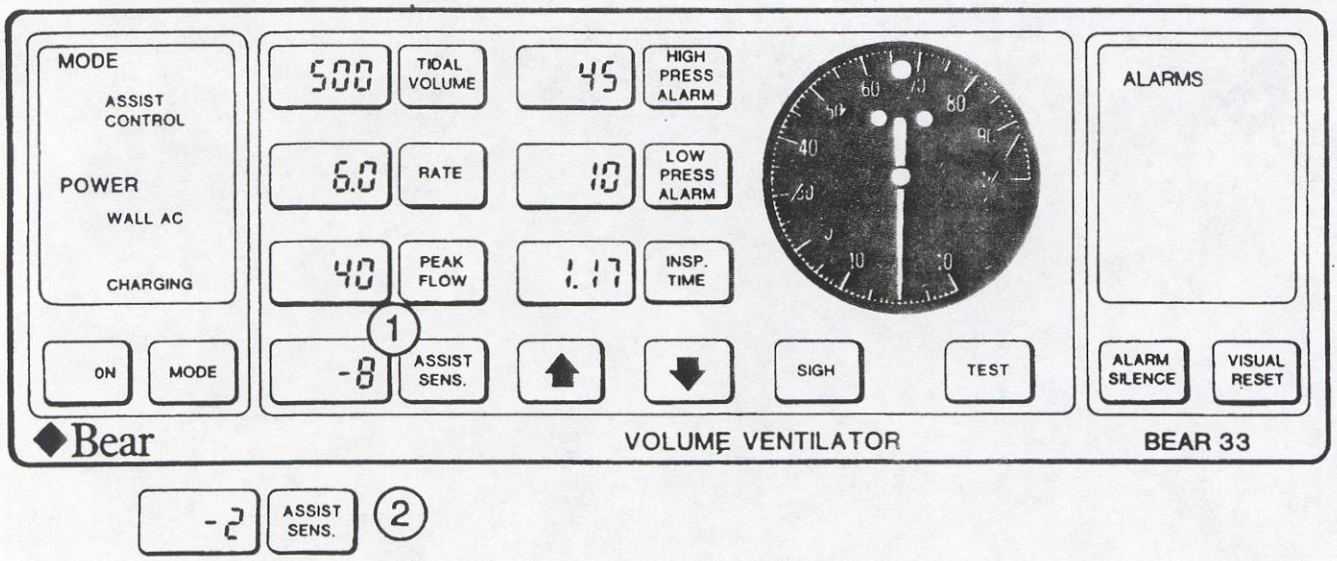


Figure 3-8A

ASSIST CONTROL MODE TEST

1. UNLOCK the panel and set all displays to the initial values indicated in Figure 3-8A.
2. Allow the ventilator to cycle at least twice to stabilize all functions.
3. Fully expand the test lung bellows immediately after a positive pressure breath has been delivered (Figure 3-8B). Verify that an "A" appears briefly at the left side of the ASSIST SENS. LCD display.

NOTE

Ignore the HI PRESS LED and alarm that may result.

NOTE

Do not expand a Manley Test Lung until it has stabilized at 0.00.

4. Verify that an assisted breath is delivered.
5. Again UNLOCK the front panel and reset the ASSIST SENS. display to -2 cmH_2O (Figure 3-8A, Item 2).
6. Create a negative pressure as in Step 3, but only slightly expand the Test Lung bellows. Again, verify that an "A" appears at the left side of the ASSIST SENS. LCD display and an assisted breath is delivered.
7. Set the ASSIST SENS. display to 5 cmH_2O and verify that autocycling occurs. Autocycling is recognized by the brief appearance of an "A" in the display and simultaneous delivery of a breath on every cycle.

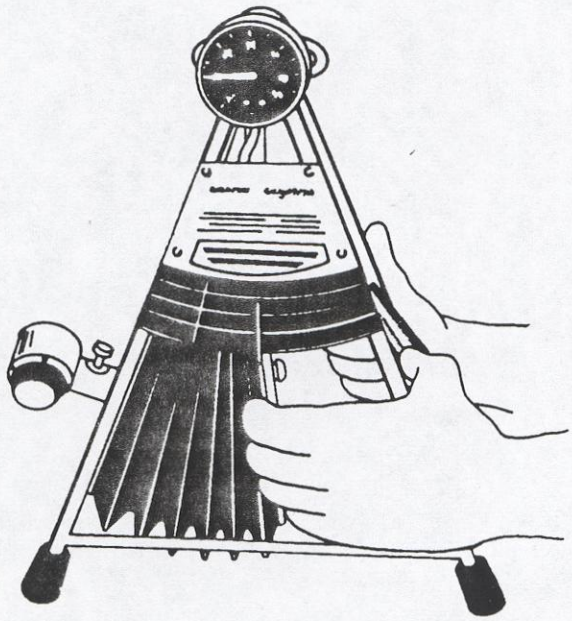


Figure 3-8B

Decrease the setting of the ASSIST SENS. display one step at a time (i.e., 4, 3, 2, etc.) to -1 cmH_2O. Verify that autocycling does occur at each display setting down to and including 1 cmH_2O. Verify that autocycling does not occur at -1 cmH_2O. Autocycling may or may not occur at 0 cmH_2O.

DISPLAY SETTINGS FOR SIMV MODE TEST

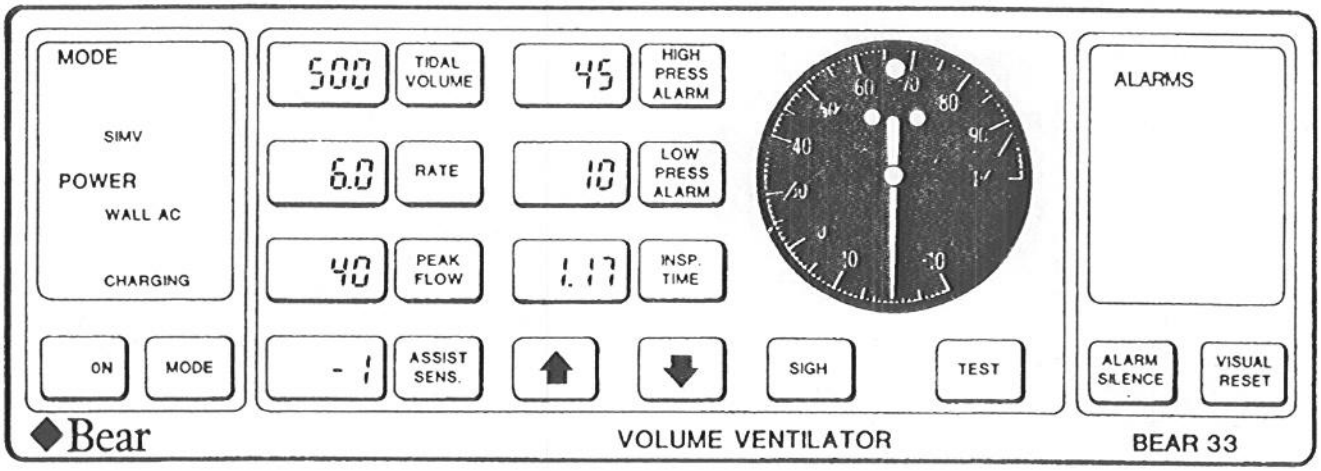


Figure 3-9A

SIMV MODE TEST

1. UNLOCK the panel and set all displays to the initial values indicated in Figure 3-9A. Allow the ventilator to cycle at least twice to stabilize all functions.
2. Expand the Test Lung (Figure 3-9B) to verify that a single ASSISTED breath, then consecutive spontaneous breaths, can be produced by pulling the bellows plate to expand the bellows.
3. Verify spontaneous breaths by continuing to periodically "pull" on the Test Lung until the next time period allows an ASSISTED breath.
4. Check the appropriate block on the OVP checklist.

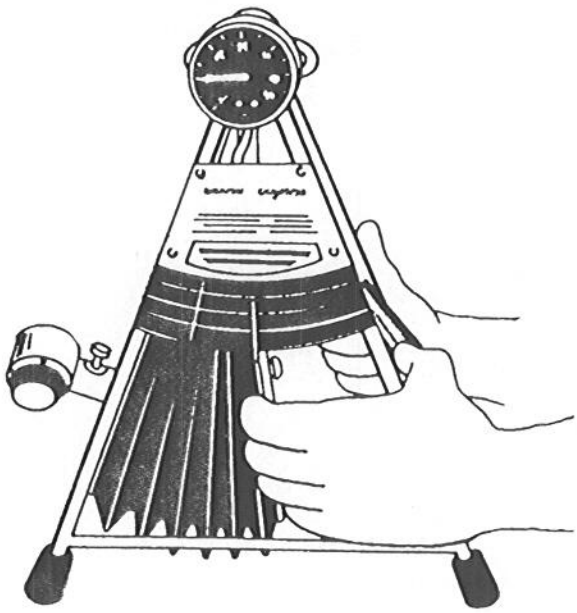


Figure 3-9B

13

DISPLAY SETTINGS FOR SIGH FUNCTION TEST

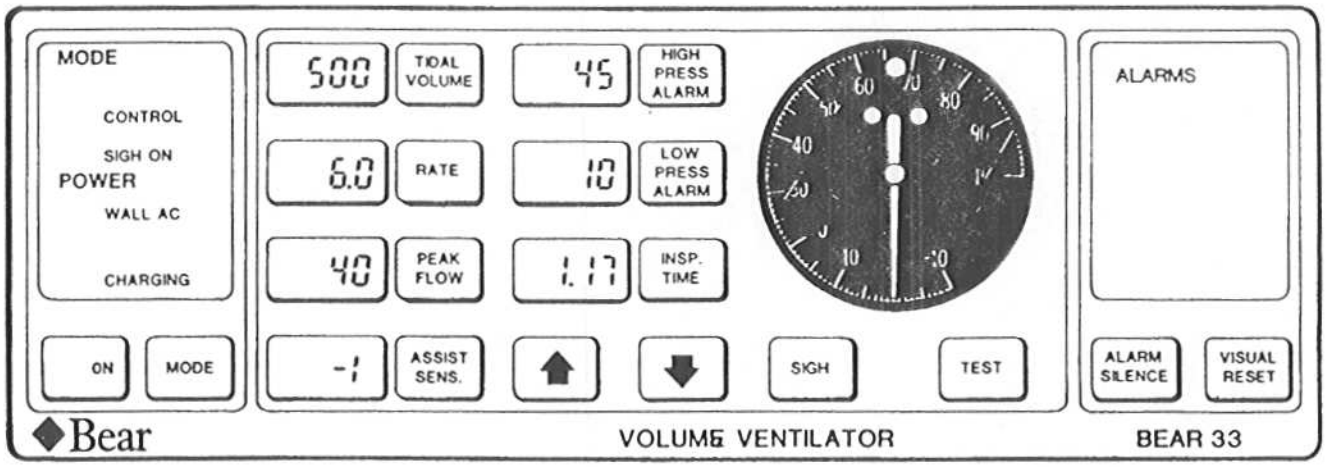


Figure 3-10

SIGH FUNCTION TEST

1. UNLOCK the front panel and set all displays to the initial values indicated in Figure 3-10. Allow the ventilator to cycle at least twice to stabilize all functions.
2. Again UNLOCK the panel and depress the SIGH button. Verify the following:
   a. The SIGH ON LED illuminates
   b. A sigh breath is delivered as indicated by the increased deflection of the PROXIMAL AIRWAY PRESSURE gauge. Since sigh breaths have 1.5 times normal tidal volumes, proximal pressure should be approximately 1.5 times normal at the end of volume delivery.
   c. The SIGH ON LED blinks momentarily during the sigh breath.
3. Check the appropriate block on the QVP checklist.

NOTE

There will be a 1-2 breath delay after depressing the SIGH button before the SIGH BREATH is delivered.

DISPLAY SETTINGS FOR TIDAL VOLUME DISPLAY TEST

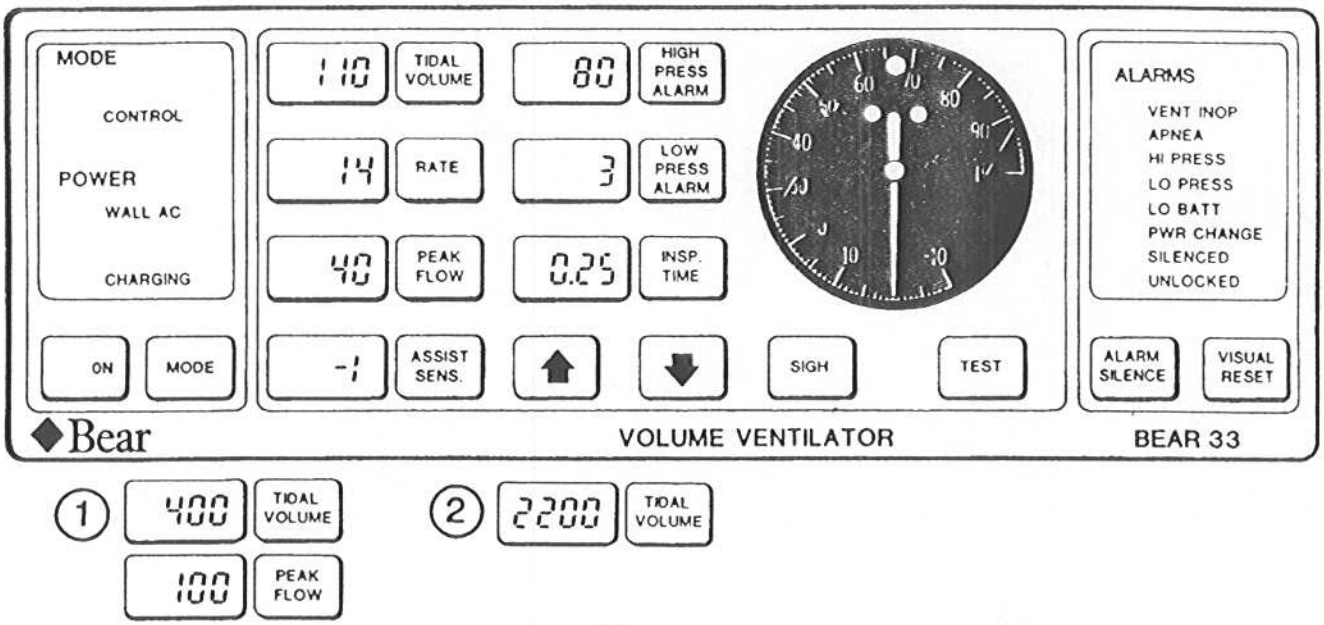


Figure 3-11

TIDAL VOLUME DISPLAY FUNCTION TEST

1. UNLOCK the front panel and set all displays to the initial values indicated in Figure 3-11. Allow the ventilator to cycle at least twice to stabilize all functions.
2. Verify that the TIDAL VOLUME LCD display flashes as long as the DOWN button and the TIDAL VOLUME display button are held depressed at the 110 ml setting.

NOTE

Ignore the audible alarm and alarm LED display that may occur during these tests.

3. Increase the TIDAL VOLUME LCD display to 400 ml, then increase the PEAK FLOW LCD display to 100 LPM (Figure 3-11, Item 1).
4. Depress the UP button and the TIDAL VOLUME LCD display button until a reading of 2200 ml is displayed (Figure 3-11, Item 2). Verify that the TIDAL VOLUME LCD display flashes as long as these buttons are held depressed at the 2200 ml setting.
5. Check the appropriate block on the OVP checklist.

15

DISPLAY SETTINGS FOR RATE TEST

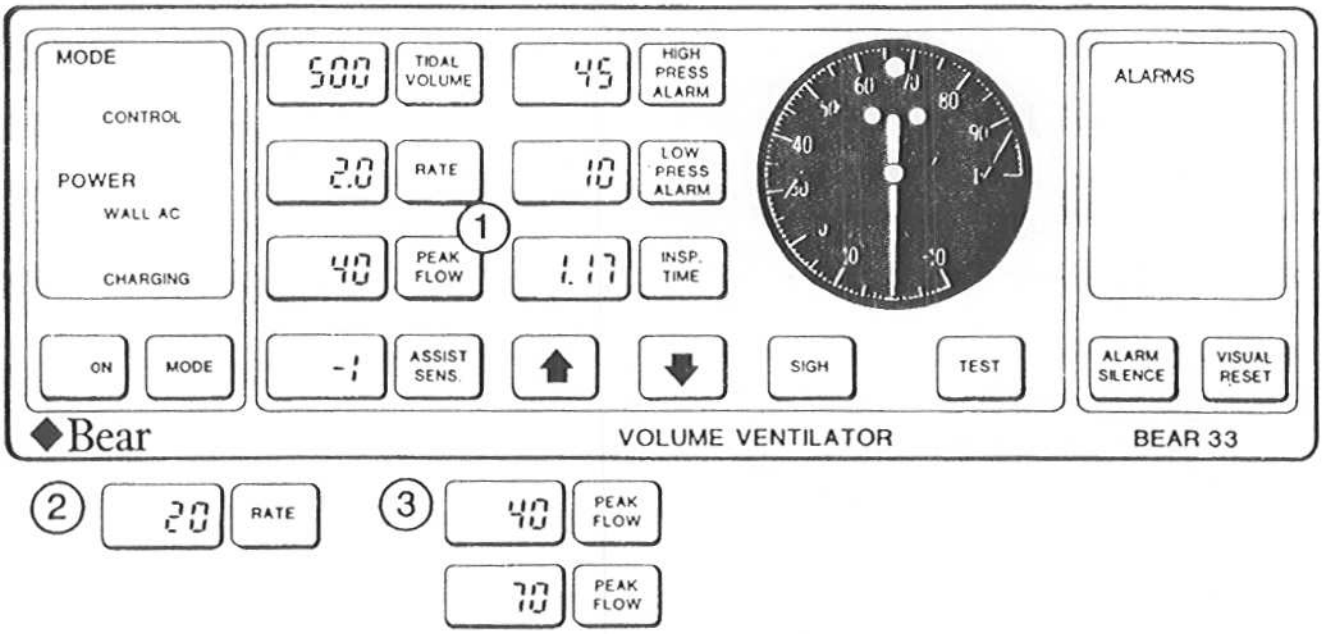


Figure 3-12

RATE TEST

1. UNLOCK the front panel and set all displays to the initial values indicated in Figure 3-12. Allow the ventilator to cycle at least twice to stabilize all functions.
   Verify that the RATE LCD display flashes as long as the DOWN button and the RATE LCD display button are held depressed at the 2 BPM setting (Figure 3-12, Item 1).

NOTE

Ignore the audible alarm and APNEA LED display that may occur during these tests.

3. Use the stopwatch to time a one-minute period and count the number of delivered breaths during that period. The count must be 2 BPM ±1 BPM.
4. Increase the setting of the RATE LCD display to 20 BPM (Figure 3-12, Item 2). Again, time a one-minute period and count the number of delivered breaths. The count must be 20 BPM ±1 BPM.
5. Increase the setting of the PEAK FLOW LCD display to 70, then increase the setting of the RATE LCD display to 40 BPM (Figure 3-12, Item 3). The number of delivered breaths in one minute must be 40 BPM ±2 BPM.
6. Verify that the RATE LCD display flashes as long as the UP button and the RATE display button are held depressed at the 40 BPM setting.
7. Check the appropriate block on the OVP checklist.

DISPLAY SETTINGS FOR PEAK FLOW DISPLAY TEST

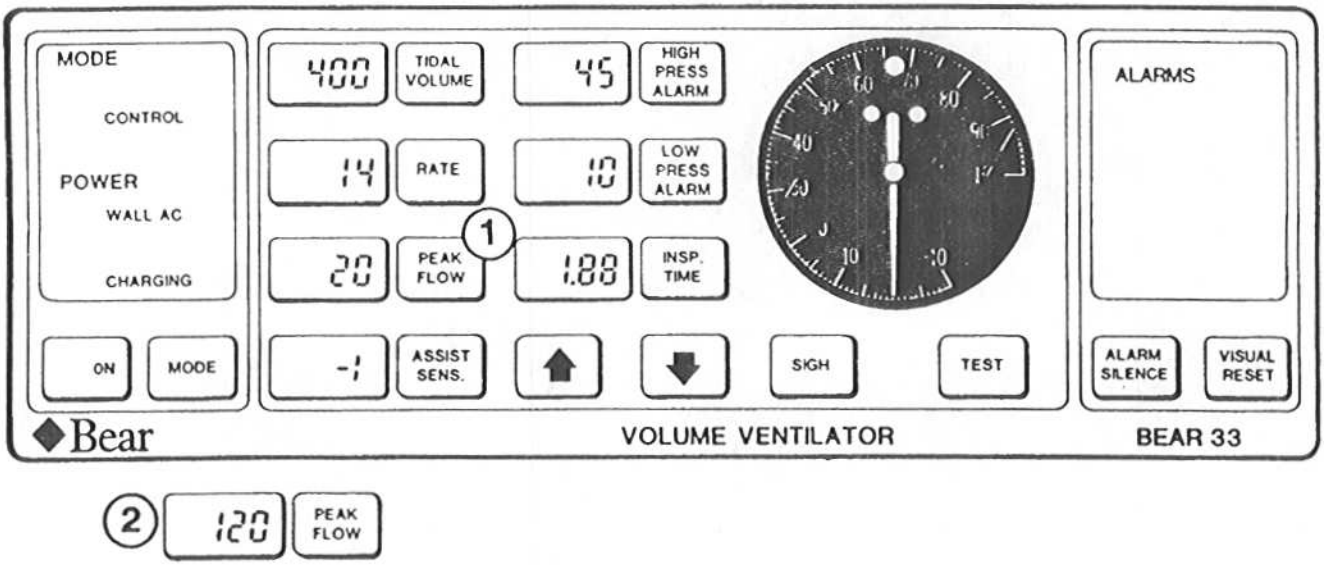


Figure 3-13

PEAK FLOW DISPLAY FUNCTION TEST

1. UNLOCK the front panel and set all displays to the initial values indicated in Figure 3-13. Allow the ventilator to cycle at least twice to stabilize all functions.
2. With the panel unlocked, verify that the PEAK FLOW LCD display continues to flash as long as the DOWN button and the PEAK FLOW display button are held depressed at the 20 LPM setting (Figure 3-13, Item 1).

NOTE

Ignore the audible and visual alarms that may occur during these tests.

3. Change the PEAK FLOW LCD display to 120 LPM (Figure 3-13, Item 2). Verify that the display continues to flash as long as the UP button and the PEAK FLOW display button are held depressed at the 120 LPM setting.
4. Check the appropriate block on the OVP checklist.

DISPLAY SETTINGS FOR ASSIST SENSITIVITY DISPLAY FUNCTION TEST

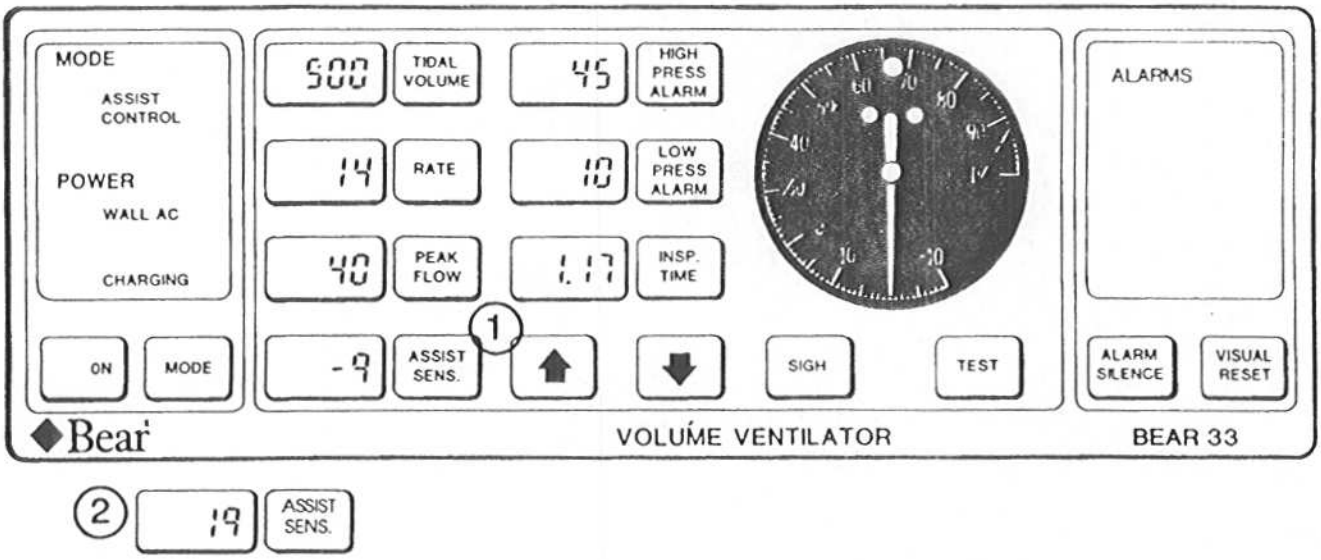


Figure 3-14

ASSIST SENSITIVITY DISPLAY FUNCTION TEST

1. UNLOCK the front panel and set all displays to the initial values indicated in Figure 3-14. Allow the ventilator to cycle at least twice to stabilize all functions.
2. With the panel unlocked, verify that the ASSIST SENS. LCD display continues to flash as long as the DOWN button and the ASSIST SENS. display button are held depressed at the -9 cmH_2O setting (Figure 3-13, Item 1).
3. Change the ASSIST SENS. LCD display to 19 cmH_2O (Figure 3-13, Item 2). Verify that the display continues to flash as long as the UP button and the ASSIST SENS. display button are held depressed at the 19 cmH_2O setting.
4. Check the appropriate block on the OVP checklist.

DISPLAY SETTINGS FOR PROXIMAL AIRWAY PRESSURE GAUGE TEST

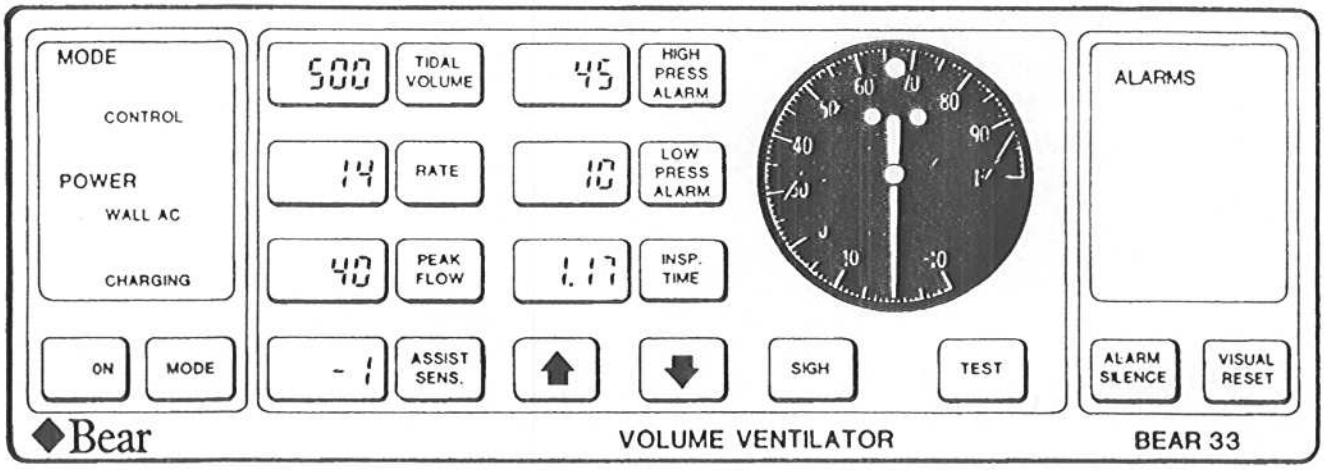


Figure 3-15A

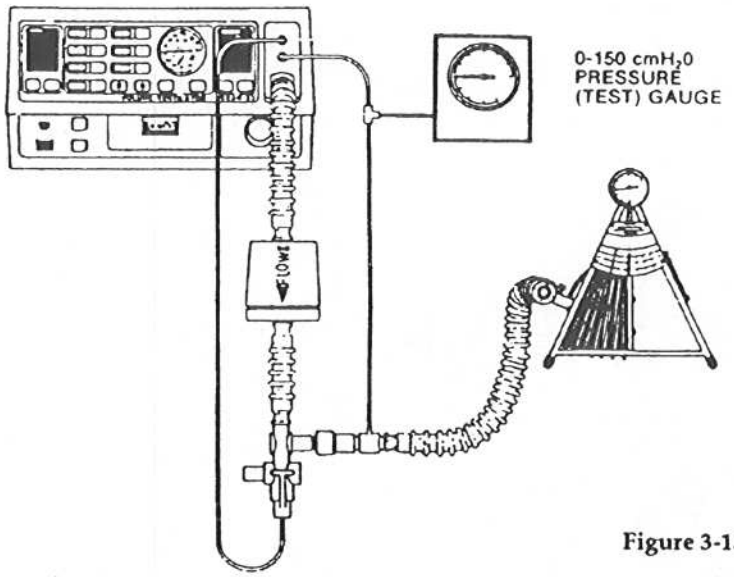


Figure 3-15B

PROXIMAL AIRWAY PRESSURE GAUGE TEST

1. Connect a 0-150 cmH2O Pressure Test gauge into the PROXIMAL PRESSURE SENSING LINE as indicated in Figure 3-15B above.
2. UNLOCK the front panel and set all displays to STANDARD SETTINGS (Figure 3-15A). Allow the ventilator to cycle at least twice to stabilize all functions.
3. Verify that the pointers on the PROXIMAL AIRWAY PRESSURE GAUGE and the Test Gauge return to zero during the exhalation phase.
4. Verify that the peak reading on the PROXIMAL AIRWAY PRESSURE GAUGE is within ±3 cmH2O of the peak reading on the Test Gauge.
5. Check the appropriate block on the OVP checklist.

STANDARD DISPLAY SETTINGS FOR TESTS

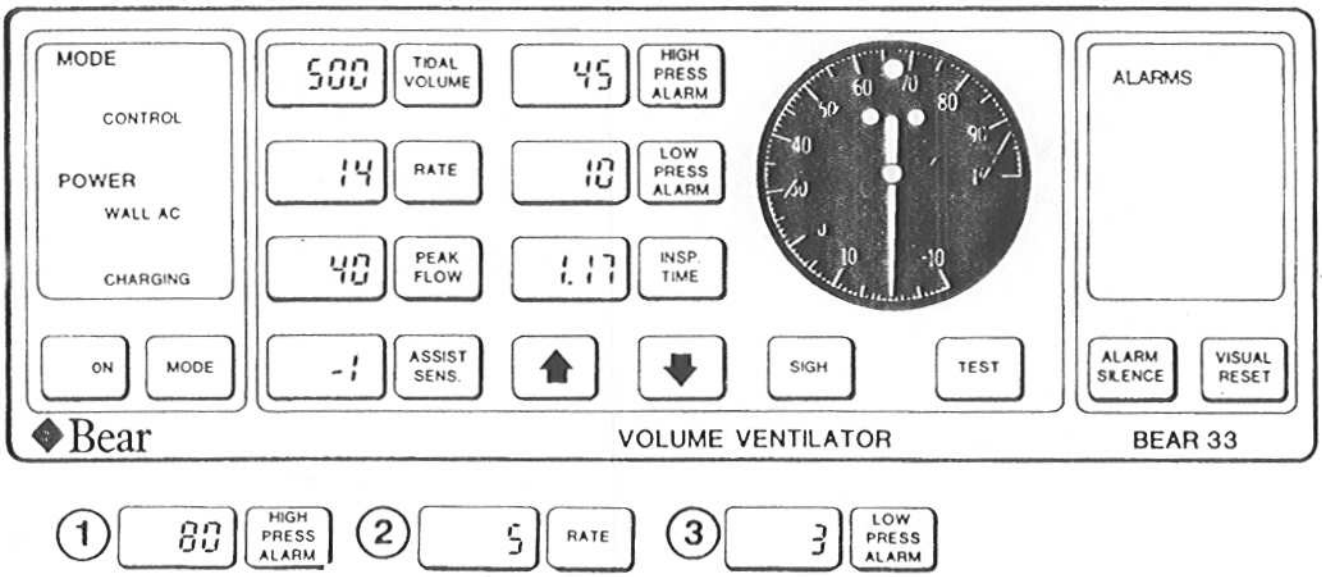


Figure 3-16

HIGH PRESS ALARM AND APNEA ALARM

A. Operation Below 80 cmH_2O
   1. UNLOCK the front panel and set all displays to STANDARD SETTINGS (Figure 3-16). Allow the ventilator to cycle at least twice to stabilize all functions.
   2. Carefully observe the peak pressure indicated on the PROXIMAL AIRWAY PRESSURE gauge. Reduce the HIGH PRESS ALARM LCD setting to a value 5 cmH_2O less than the peak pressure reading.
   3. Verify that after the first positive pressure breath which exceeds the HIGH PRESS ALARM setting:
      a. The HI PRESS alarm display starts flashing,
      b. Volume delivery is terminated and the PROXIMAL AIRWAY PRESSURE GAUGE falls back to zero,
      c. The audible alarm does not sound.
   4. Verify that, after the second positive pressure breath which exceeds the HIGH PRESS ALARM setting:
      a. The audible alarm sounds
      b. Volume delivery is terminated and the PROXIMAL AIRWAY PRESSURE GAUGE falls back to zero
      c. The HI PRESS alarm display continues flashing.
   5. Increase the HIGH PRESS ALARM LCD setting to a value 5 cmH_2O greater than the peak pressure reading noted in step 2.
   6. Verify that:
      a. The audible alarm stops,
      b. The HI PRESS alarm display continues flashing until the VISUAL RESET button is depressed.

B. Operation Above 80 cmH_2O
   1. UNLOCK the front panel and set all displays to STANDARD SETTINGS except set the HIGH PRESS ALARM LCD display to 80 cmH_2O (Figure 3-16, Item 1). Allow the ventilator to cycle at least twice to stabilize all functions.
   2. Disconnect the flextube from the test lung and occlude the end of the tube.
   3. Verify that, after the first positive pressure breath delivered with the tube occluded:
      a. The HI PRESS alarm display starts flashing,
      b. The audible alarm sounds,
      c. Volume delivery is terminated and the PROXIMAL AIRWAY PRESSURE GAUGE falls back to zero

C. Operation Under Prolonged Inspiratory Pressure
   1. Reconnect the standard OVP test circuit and return all ventilator displays to STANDARD SETTINGS except set the RATE LCD display to 5 BPM (Figure 3-16, Item 2). Allow the ventilator to cycle at least twice to stabilize all functions.
   2. Immediately following a delivered breath, occlude the patient manifold exhalation port by connecting a one-way check valve in reverse.

3. Verify that, at the first positive pressure breath following occlusion of the port which exceeds the HIGH PRESS alarm setting:
   a. The HI PRESS alarm display starts flashing,
   b. Volume delivery is terminated.
4. Start the stopwatch immediately when the HI PRESS alarm display turns on and verify that:
   a. After approximately three seconds the audible alarm sounds,
   b. In approximately 20 seconds, the APNEA alarm display turns on.
5. Remove the occluding valve from the patient manifold and turn the ventilator power OFF, then back ON. Allow the ventilator to cycle at least twice to stabilize all functions.
6. Again occlude the patient manifold exhalation port with the one-way check valve and wait until the APNEA alarm display turns on. Remove the occluding check valve from the manifold and verify that:
   a. The audible alarm STOPS,
   b. Normal cycling resumes and the APNEA alarm display is turned off by depressing the VISUAL RESET button.
7. Check the HIGH PRESSURE ALARM and APNEA blocks on the OVP checklist.

LOW PRESS ALARM AND PATIENT DISCONNECT

1. UNLOCK the front panel and set all displays to STANDARD SETTINGS except set the LOW PRESS ALARM LCD display to 3 cmH_2O (Figure 3-16, Item 3). Allow the ventilator to cycle at least twice to stabilize all functions.
2. Disconnect the flextube from the test lung.
3. Verify that, on the first positive pressure breath following the flextube disconnection:
   a. The LO PRESS display alarm starts flashing,
   b. The audible alarm does not sound.
4. Verify that, on the second positive pressure breath delivered:
   a. The audible alarm sounds,
   b. The LO PRESS display alarm continues flashing.
5. Reconnect the test lung and verify that:
   a. The audible alarm stops,
   b. The LO PRESS display alarm is turned off by depressing the VISUAL RESET button.
3. Check the appropriate blocks on the OVP checklist for LOW PRESSURE ALARM and PATIENT DISCONNECT.

STANDARD DISPLAY SETTINGS FOR DELIVERED VOLUME TEST

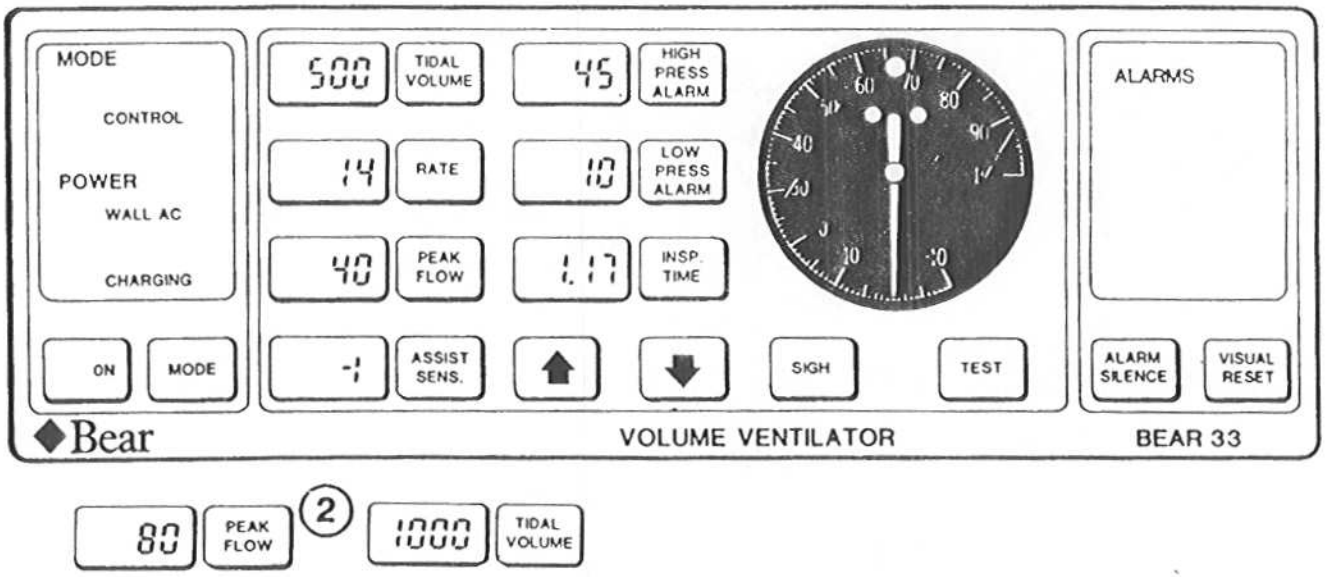


Figure 3-17A

DELIVERED VOLUME TEST

1. Reconnect the test circuit as in Figure 3-17B, with the spirometer replacing the test lung.
2. UNLOCK the front panel and adjust all displays to STANDARD SETTINGS (Figure 3-17A). Allow the ventilator to cycle at least twice to stabilize all functions.
3. Disconnect the 3/4" hose from the spirometer, zero the spirometer, and reconnect the hose to the spirometer during an exhalation phase of the ventilator.
4. Allow the ventilator to deliver 10 breaths and disconnect the spirometer hose before the eleventh breath begins. Verify that the spirometer reads 5.0L ±0.25L.
5. Reconnect the spirometer hose. Increase the PEAK FLOW LCD display to 80 LPM and the TIDAL VOLUME LCD display to 1000 ml (Figure 3-17A, Item 2).
6. Disconnect the spirometer hose, zero the spirometer, and reconnect the hose during an exhalation phase of the ventilator.
7. Allow the ventilator to deliver two breaths and disconnect the spirometer hose before the third breath begins. Verify that the spirometer reads 2.0L ±0.1L.
8. Check the appropriate block on the OVP checklist.

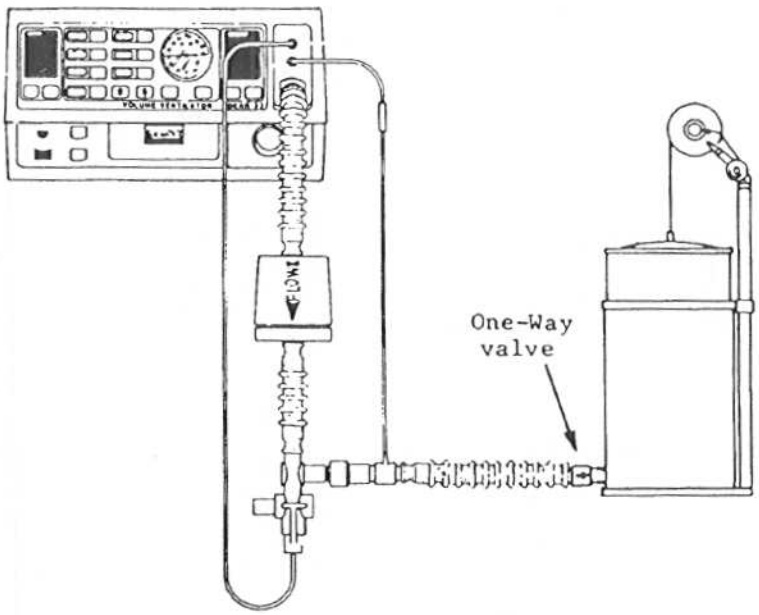


Figure 3-17B

DISPLAY SETTINGS FOR OVERPRESSURE RELIEF VALVE TEST

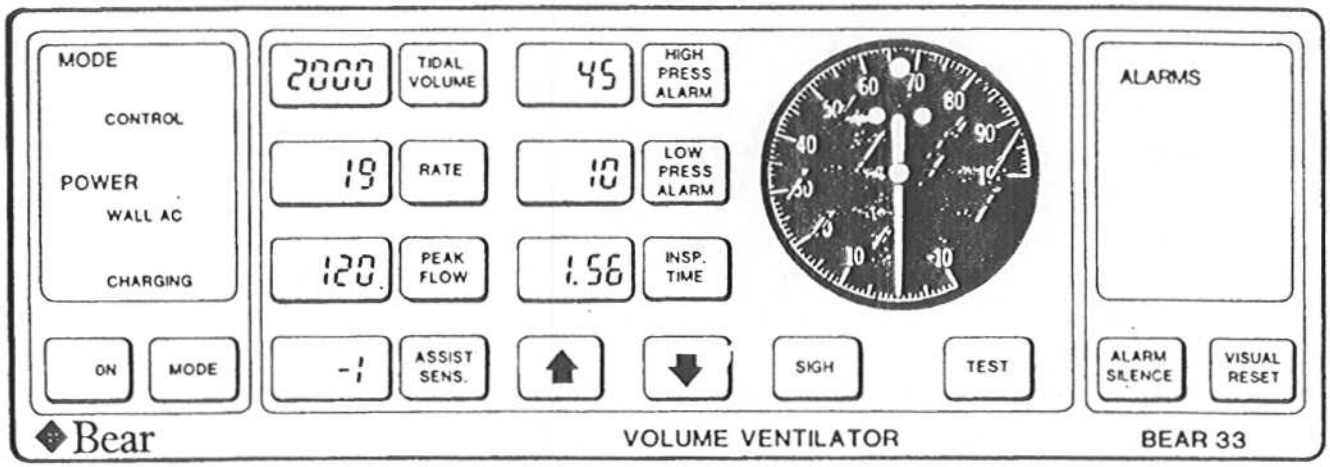


Figure 3-18A

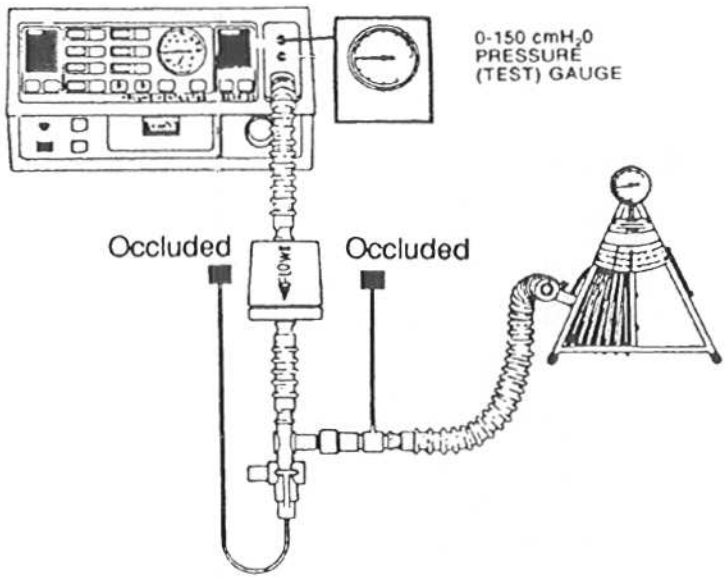


Figure 3-18B

OVERPRESSURE RELIEF VALVE TEST

1. Reconnect the test circuit as in Figure 3-18B. The Manley Test Lung is set at C10/R5.
2. Turn ventilator power ON and set all displays to the initial values in Figure 3-18A.

WARNING

IF THE TEST GAUGE READING APPROACHES 150 cmH_2O, IMMEDIATELY TURN UNIT OFF TO AVOID EXCESSIVE PRESSURE, CAUSING DAMAGE TO THE UNIT OR THE OPERATOR.

3. Verify that pressure indicated on the test gauge does not exceed 125 cmH_2O.

NOTE

Ignore the LO PRESS LED and audible alarm.

4. If system pressure does not exceed 125 cmH_2O, repeat step three twice.
5. Check the appropriate block on the OVP checklist.

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BEAR® 33 VOLUME VENTILATOR
OPERATIONAL VERIFICATION CHECK LIST

This checklist is for use during the BEAR® 33 Operational Verification

BEAR® 33 Serial Number_____ Hour meter reading_____ Today's date _____

Service Location	_____	Service organization	_____
Address	_____	Address	_____
City, State, Zip	_____	City, State, Zip	_____
Contact	_____	Service Person	_____
Phone (___)	_____	Phone (___)	_____

VERIFICATION STEPS

STEP	OPERATION	TEST RESULTS	ACCEPT	UNACCEPT
General Inspection	Clean and check	As specified	❑	❑
Display & Alarm Test	Perform test	As specified	❑	❑
Power Up	Verify	As specified	❑	❑
System Leak Test				
Proximal Airway Pressure	Perform Test	As specified	❑	❑
Baseline Pressure	Perform Test	As specified	❑	❑
CONTROL MODE	Verify	As specified	❑	❑
ASSIST CONTROL MODE	Verify	As specified	❑	❑
SIMV MODE	Verify	As specified	❑	❑
SIGH Function	Verify	As specified	❑	❑
Tidal Volume Display	Verify	As specified	❑	❑
Rate	Verify	As specified	❑	❑
Peak Flow Display	Verify	As specified	❑	❑
Assist Sensitivity Display	Verify	As specified	❑	❑
Proximal Airway Pressure Gauge	Verify	As specified	❑	❑
High Pressure Alarm	Verify	As specified	❑	❑
Apnea	Verify	As specified	❑	❑

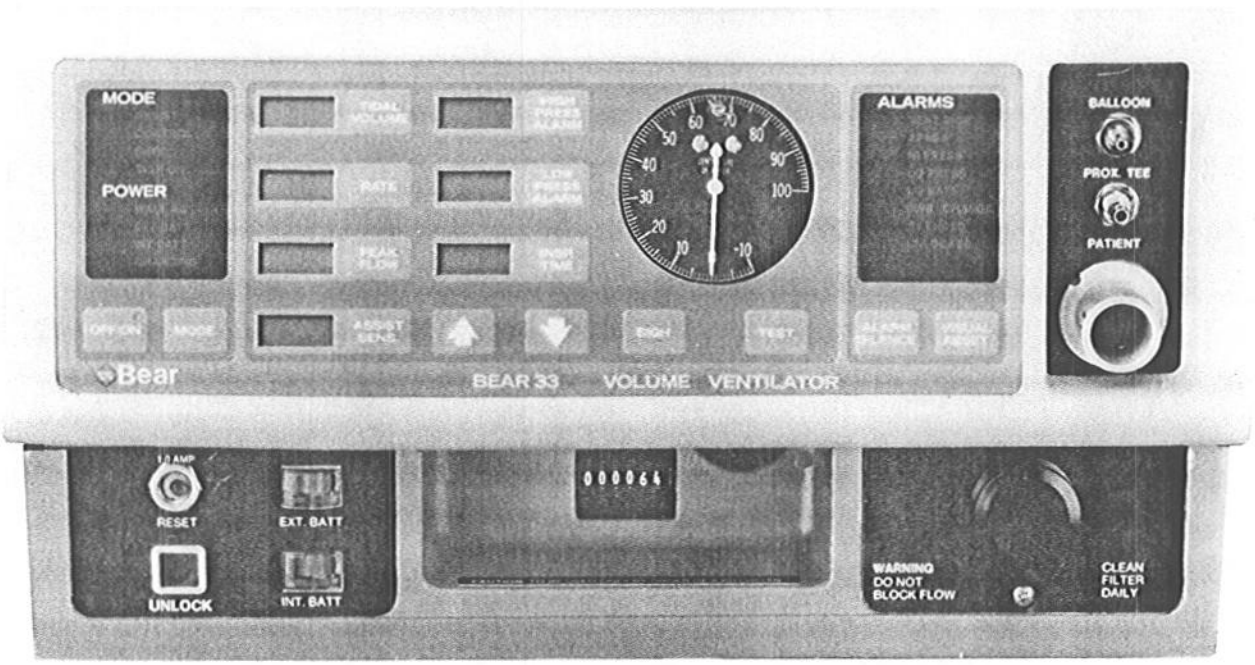
Low Pressure.Alarm	Verify	As specified	❑	❑
Patient Disconnect	Verify	As specified	❑	❑
STEP	OPERATION	TEST RESULTS	ACCEPT	UNACCEPT
Delivered Volume	Verify	As specified	❑	❑
LOW EXH. VOL Alarm	Check alarm	As specified	❑	❑
Overpressure Relief Valve	Verify	As specified	❑	❑

WARNING

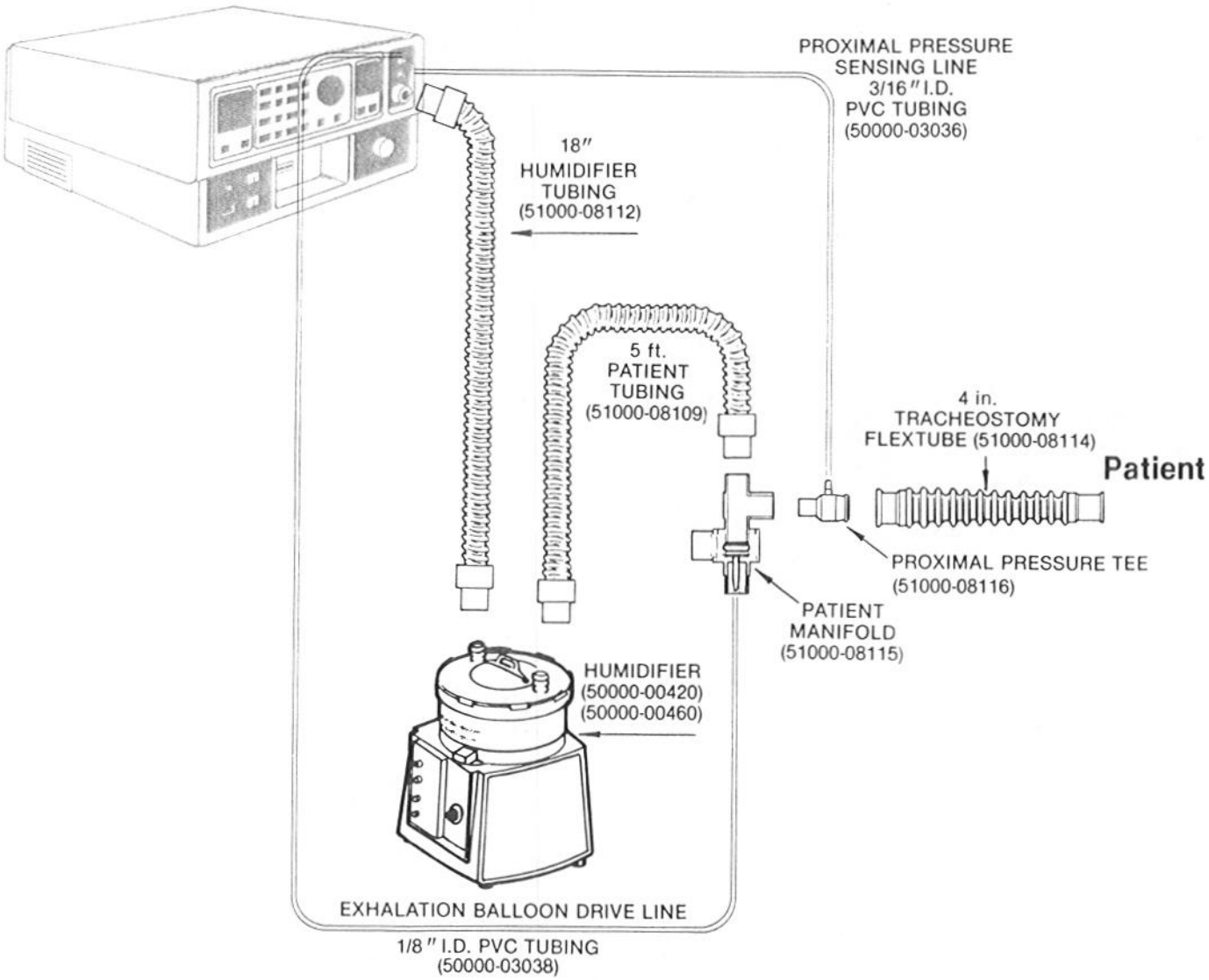
DO NOT RELEASE THE VENTILATOR FOR USE IF IT DOES NOT PASS ALL OF THE VERIFICATION PROCEDURES SPECIFIED IN THE CHECKLIST. TO DO SO COULD RESULT IN PERSONAL INJURY OR PROPERTY DAMAGE. REFER THE VENTILATOR TO A BEAR MEDICAL SYSTEMS SERVICE TECHNICIAN, A BEAR MEDICAL SYSTEMS AUTHORIZED SERVICING DEALER, OR A BEAR MEDICAL SYSTEMS TRAINED HOSPITAL SERVICE TECHNICIAN FOR APPROPRIATE REPAIR AND/OR CALIBRATION.

Signature_____

PROCEDURE COMPLETE


MODE
POWER
ALARMS
BALLOON
PROX. TEE
PATIENT
Bear
BEAR 33 VOLUME VENTILATOR
1.0 AMP
RESET
EXT. BATT
UNLOCK
INT. BATT
000064
WARNING
DO NOT
BLOCK FLOW
CLEAN
FILTER
DAILY

40



ASSEMBLY OF PATIENT CIRCUIT
WITH LS 420/460 OR EQUIVALENT
HUMIDIFIER

Figure 13

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To prepare the BEAR® 33 Volume Ventilator for patient use, the following instructions should be read.

CIRCUIT ASSEMBLY

The BEAR® 33 Volume Ventilator (50000-00833) comes complete with a patient circuit kit. This patient circuit kit provides all the components needed to assemble any of the following circuits:

1. Circuit to be used with an LS 420/460 or equivalent humidifier; or

2. Circuit to be used with a condenser humidifier (artificial nose); or

3. Circuit without a humidifier.

A main flow bacteria filter must also be used. A separate kit (51000-08104) will be required.

Refer to the appropriate circuit assembly instructions needed and check to make sure all components are readily available.

ASSEMBLY OF PATIENT CIRCUIT WITH LS 420/460 OR EQUIVALENT HUMIDIFIER

Accessories needed:

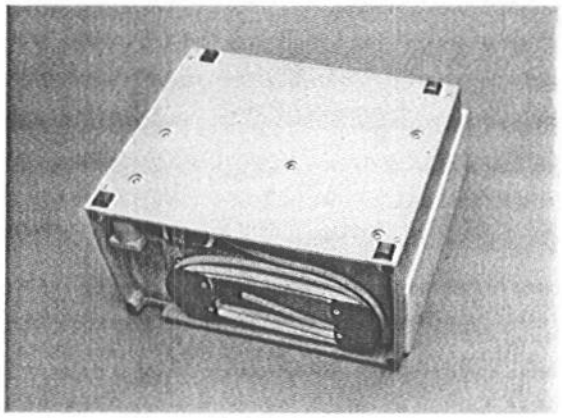
Patient Circuit Kit	(51000-08020)
Adult Humidifier or	(50000-00420)
Infant Humidifier	(50000-00460)
Humidifier Bracket, Table Mount	(51000-08124)

Refer to Figure 13.

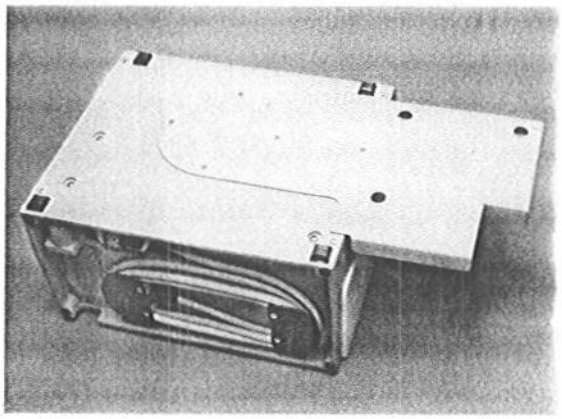
1. To assemble the LS 420/460 humidifier, refer to the Humidifier Clinical Instruction Manual (50000-10420).

NOTE

The slide mount packaged with the LS 420/460 will not be used unless the unit is to be pole mounted.



2. Place the BEAR® 33 Volume Ventilator upside-down on a flat, stable surface.



3. Attach the Table Mount Humidifier Bracket (51000-08124) to the bottom surface of the ventilator with the five (5) screws provided. Tighten the screws. Note: Do not apply excessive force or overtighten.

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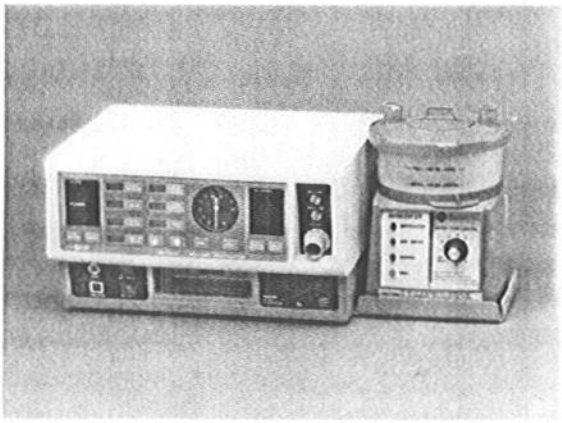


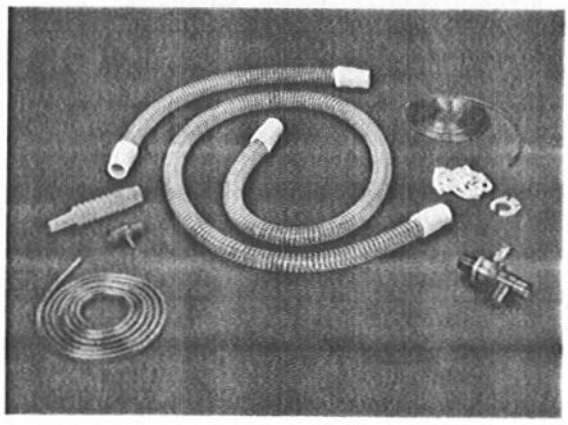
4. Place the ventilator in an upright position and set the humidifier control module on to the table mount bracket, making sure the control module feet slip into the bracket.

WARNING

Always mount the humidifier below the level of the patient and drape the patient circuit so that condensate does not drain toward the patient. Frequently drain condensate from the delivery tubes to avoid possible tubing occlusion and discomfort to the patient.

CAUTION

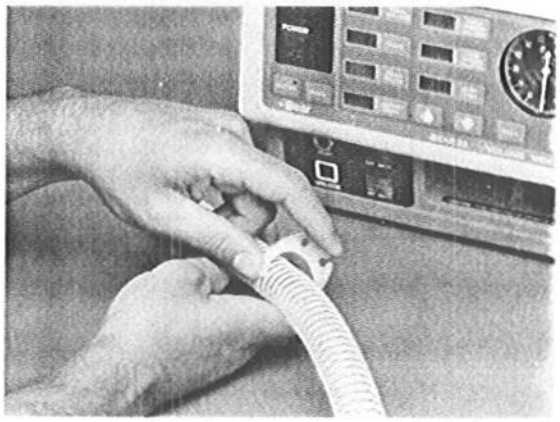
Do not use the humidifier with a patient until proper operation has been verified.



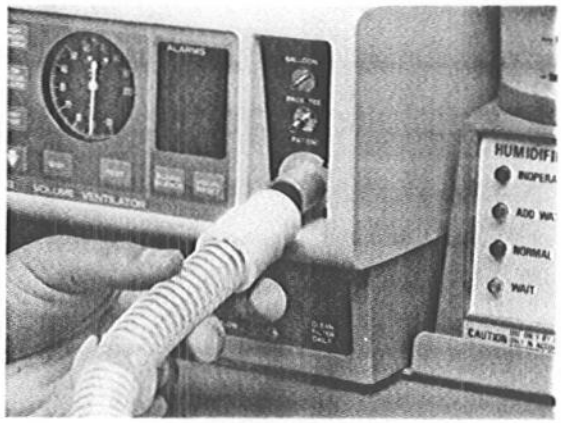
5. Lay out all the kit components:

Patient Circuit Kit

5′ Patient tubing
18″ Humidifier tubing
8′ 1/8″ I.D. PVC tubing
8′ 3/16″ I.D. PVC tubing
Proximal pressure tee
Patient manifold
4″ Tracheostomy flextube
Tubing clips (10 pack)

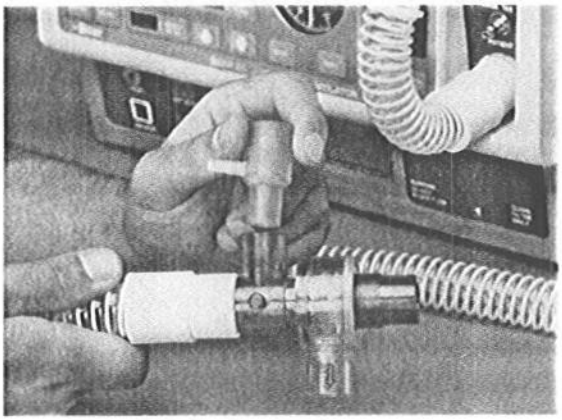


6. Attach two (2) tubing clips to the 18″ humidifier tubing.

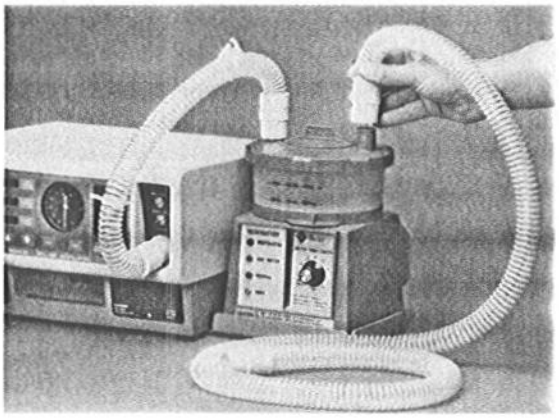


7. Fit the 18″ humidifier tubing over the 22 mm outlet connector labelled "PATIENT" on the front of the ventilator.

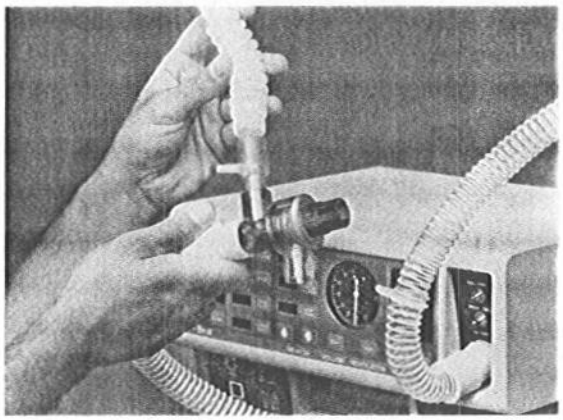
8. Connect the 18″ humidifier tubing to the inlet port of the humidifier.



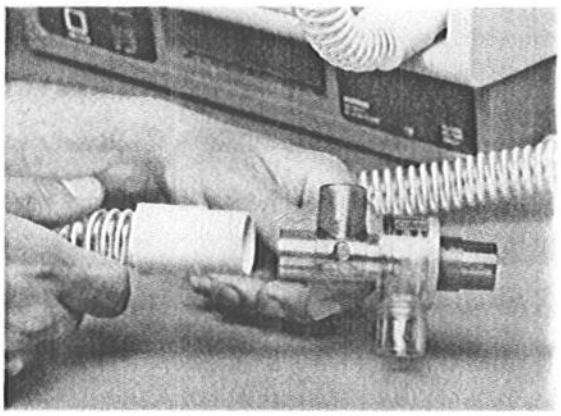
11. Connect the proximal pressure tee to the appropriate port on the patient manifold.



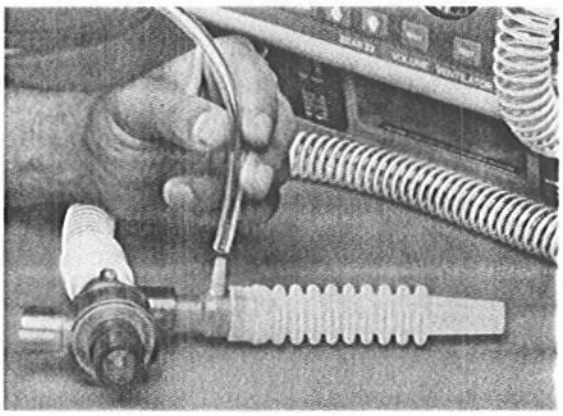
9. Connect the 5′ patient tubing to the outlet port of the humidifer.



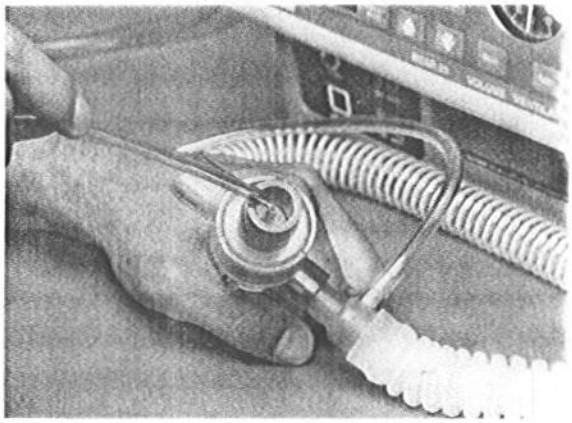
12. Connect the large end of the 4″ flextube to the free end of the proximal pressure tee.



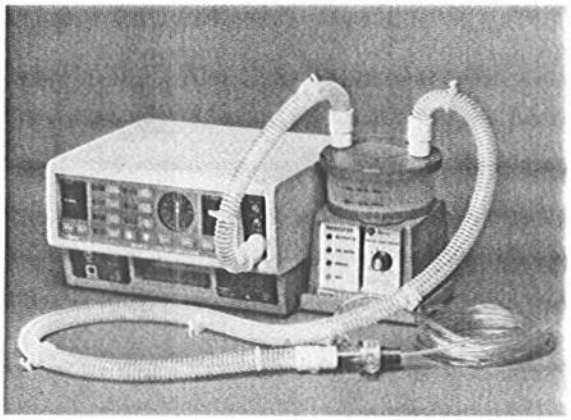
10. Connect the appropriate end of the patient manifold to the free end of the 5′ patient tubing.



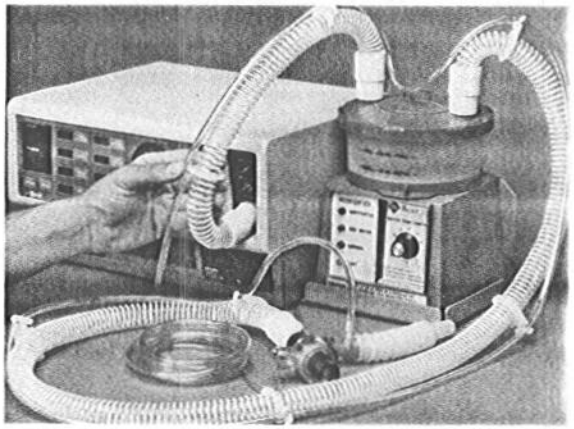
13. Connect one end of the 3/16″ I.D. PVC tubing (proximal pressure sensing line) to the single port on the proximal pressure tee.



14. Connect the 1/8″ I.D. PVC tubing (exhalation balloon drive line) to the exhalation balloon port on the patient manifold.



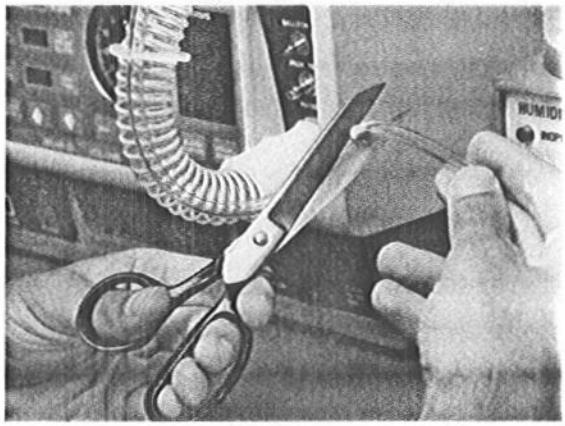
15. Attach the desired number of tubing clips to the 5′ patient tubing.



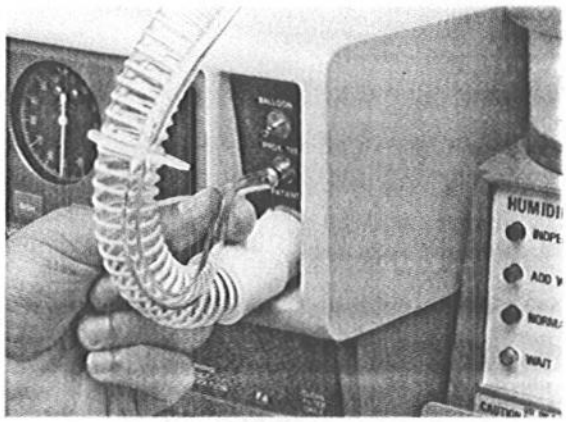
16. Attach the 3/16″ proximal pressure sensing line to the 5′ patient tubing and the 18″ humidifier tubing by snapping it into the tubing clips. Begin at the proximal pressure tee with an extra loop of tubing (as shown in the photo).

WARNING

Do not kink the proximal pressure sensing line. Kinking may result in ventilator malfunction and possible injury.



17. Trim off any excess 3/16″ tubing before attaching it to the ventilator. Do not trim the tubing too short.



18. Connect the 3/16″ proximal pressure sensing line to the 3/16″ barb fitting labelled "PROX. TEE" on the front of the ventilator.

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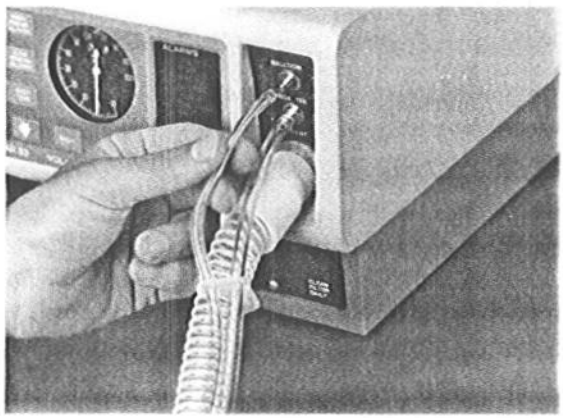
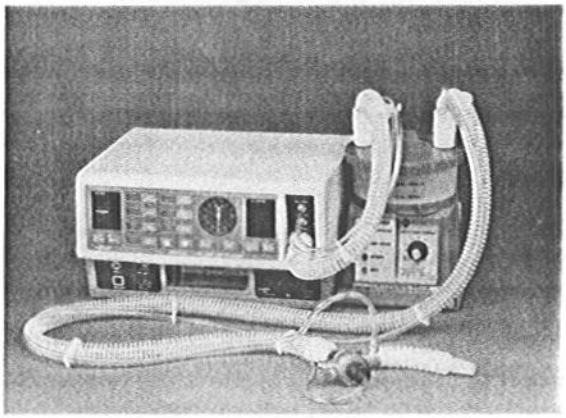
19. Repeat Steps 16 and 17 for the 1/8" exhalation balloon drive line. Begin at the patient manifold.

WARNING

Do not kink the exhalation balloon drive line. Kinking may result in ventilator malfunction and possible injury.



20. Connect the 1/8" exhalation balloon drive line to the 1/8" barb fitting labelled "BALLOON" on the front of the ventilator.



COMPLETE SET-UP OF THE BEAR® 33 VOLUME VENTILATOR WITH AN LS 420 HUMIDIFIER AND APPROPRIATE PATIENT CIRCUIT.

Figure 14

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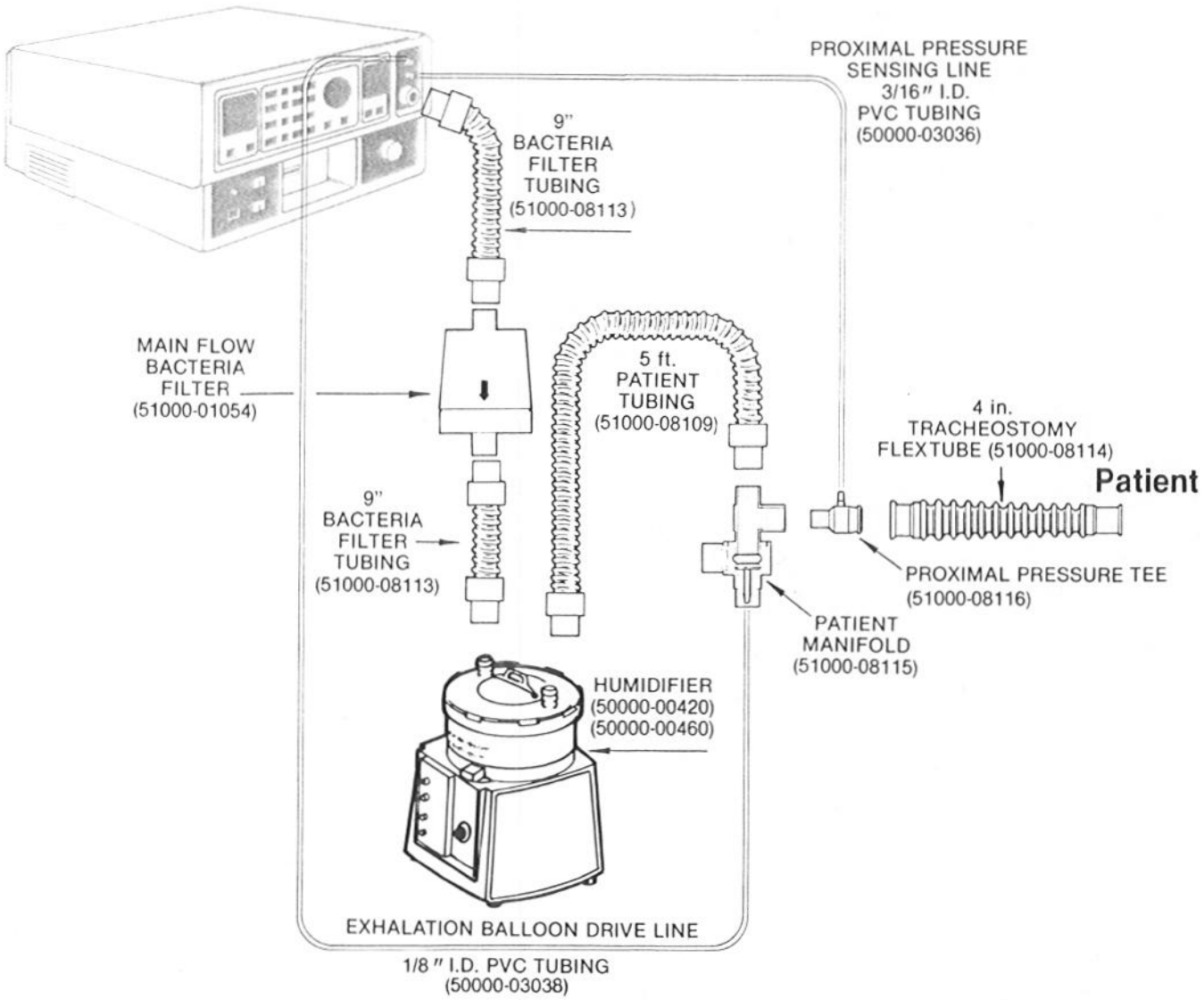


ASSEMBLY OF PATIENT CIRCUIT WITH
LS 420/460 OR EQUIVALENT HUMIDIFIER
WITH MAIN FLOW BACTERIA FILTER

Figure 15

ASSEMBLY OF PATIENT CIRCUIT WITH LS 420/460 OR EQUIVALENT HUMIDIFIER AND MAIN FLOW BACTERIA FILTER

Accessories needed:

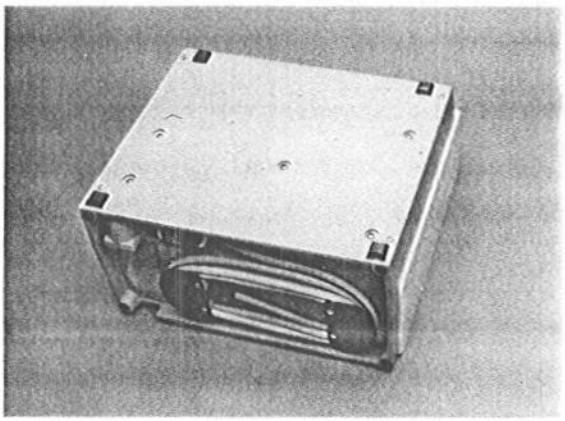
Patient Circuit Kit	(51000-08020)
Main Flow Bacteria Filter Kit	(51000-08104)
Adult Humidifier or	(50000-00420)
Infant Humidifier	(50000-00460)
Humidifier Bracket, Table Mount	(51000-08124)

Refer to Figure 15.

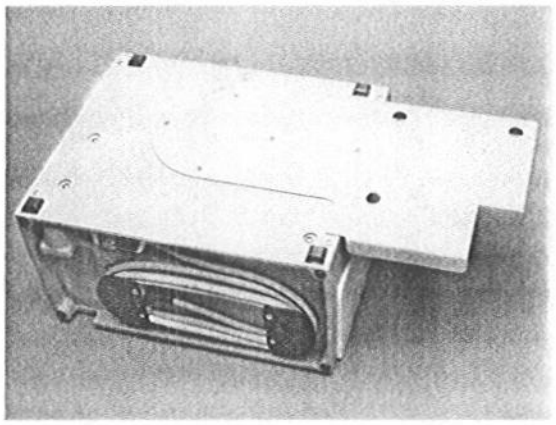
1. To assemble the LS 420/460 Humidifier, refer to the Humidifier Clinical Instruction Manual (50000-10420).

NOTE

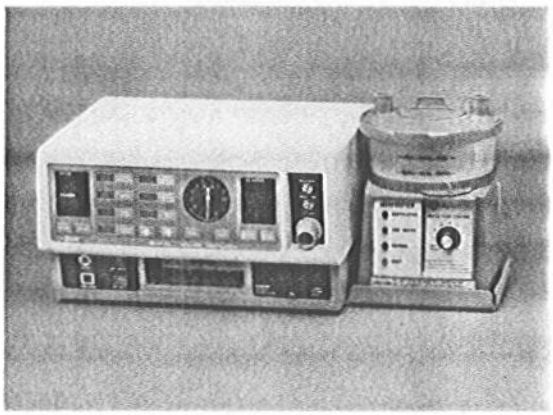
The slide mount packaged with the LS 420/460 will not be used.



2. Place the BEAR® 33 Volume Ventilator upside-down on a flat, stable surface.



3. Attach the Table Mount Humidifier Bracket (51000-08124) to the bottom surface of the ventilator with the five (5) screws provided. Tighten the screws. Note: Do not apply excessive force or overtighten.



4. Place the ventilator in an upright position and set the humidifier control module on to the table mount bracket, making sure the control module feet slip into the bracket.

WARNING

Always mount the humidifier below the level of the patient and drape the patient circuit so that condensate does not drain toward the patient. Frequently drain condensate from the delivery tubes to avoid possible tubing occlusion and discomfort to the patient.

CAUTION

Do not use the humidifier with a patient until proper operation has been verified.

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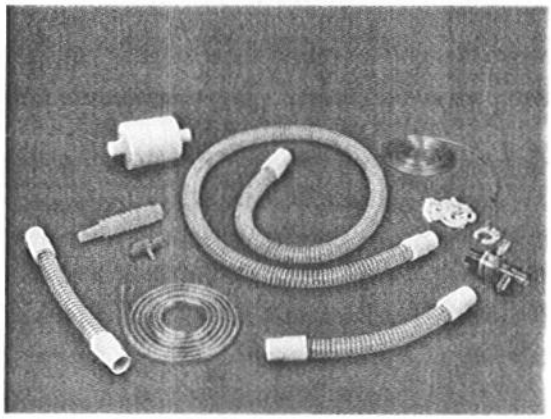
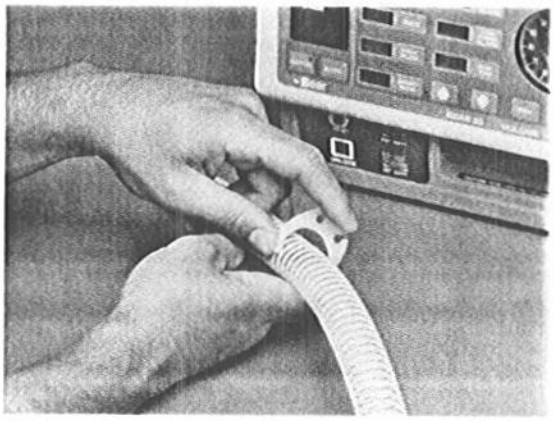


5. Lay out all the kit components:

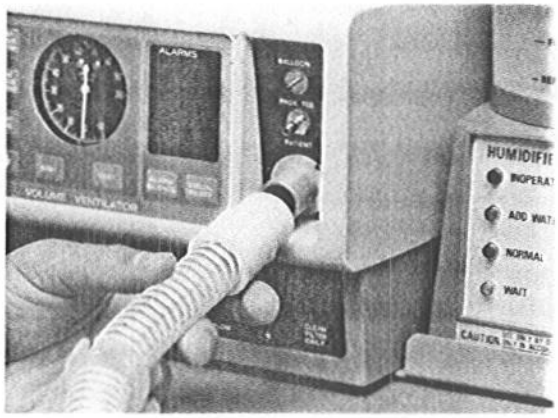
Patient Circuit Kit*
5′ Patient tubing
8′ 1/8″ I.D. PVC tubing
8′ 3/16″ I.D. PVC tubing
Proximal pressure tee
Patient manifold
4″ Tracheostomy flextube
Tubing clips (10 pack)

*NOTE: The 18″ humidifier tubing packaged in this kit will not be used.

Main Flow Bacteria Filter Kit
9″ Bacteria filter tubing (2 ea.)
Main flow bacteria filter

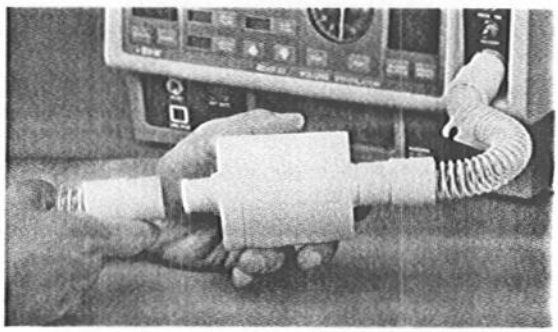


6. Attach one (1) tubing clip to each of the 9″ bacteria filter tubing.



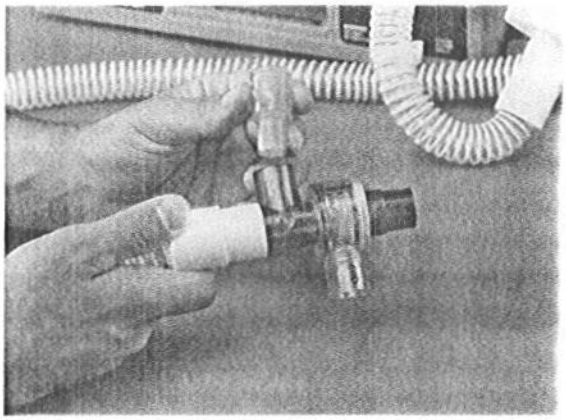
7. Fit one of the 9″ bacteria filter tubing over the 22 mm output connector labelled "PATIENT" on the front of the ventilator.

8. Attach the main flow bacteria filter to the free end of the 9″ tubing. Observe the flow direction indicated on the filter.

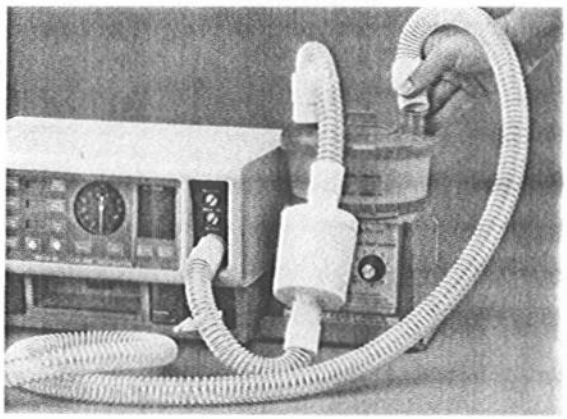


9. Attach the second 9″ bacteria filter tubing to the free end of the main flow bacteria filter.

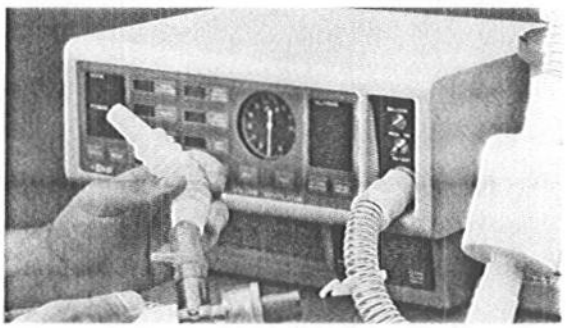
10. Connect the free end of the 9″ bacteria filter tubing to the inlet port of the humidifier.



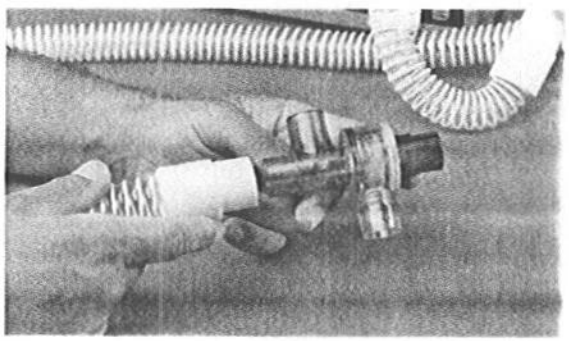
13. Connect the proximal pressure tee to the appropriate port on the patient manifold.



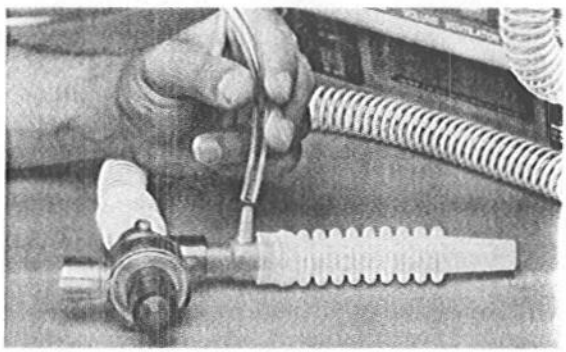
11. Connect the 5′ patient tubing to the outlet port of the humidifier.



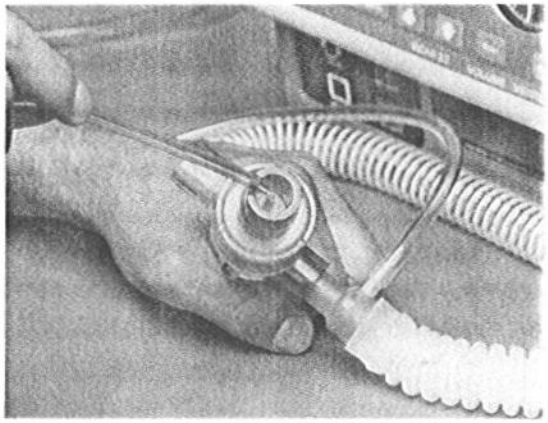
14. Connect the large end of the flextube to the free end of the proximal pressure tee.



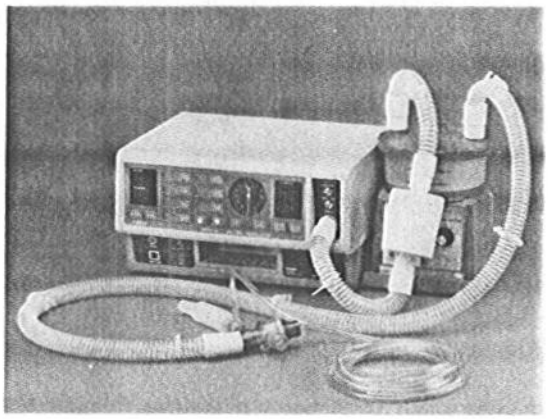
12. Connect the appropriate end of the patient manifold to the free end of the 5′ patient tubing.



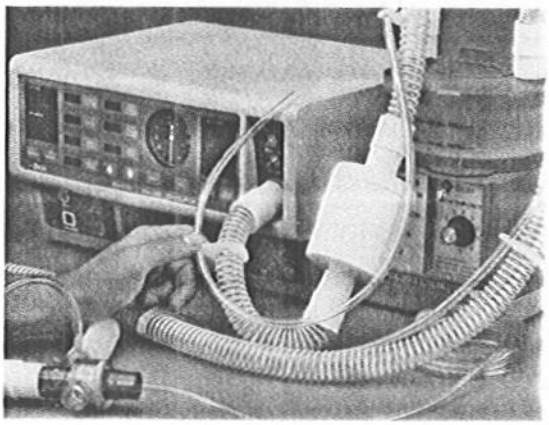
15. Connect one end of the $\frac{3}{16}$″ PVC tubing (proximal pressure sensing line) to the single port on the proximal pressure tee.



16. Connect the 1/8" I.D. PVC tubing (exhalation balloon drive line) to the exhalation balloon port on the patient manifold.



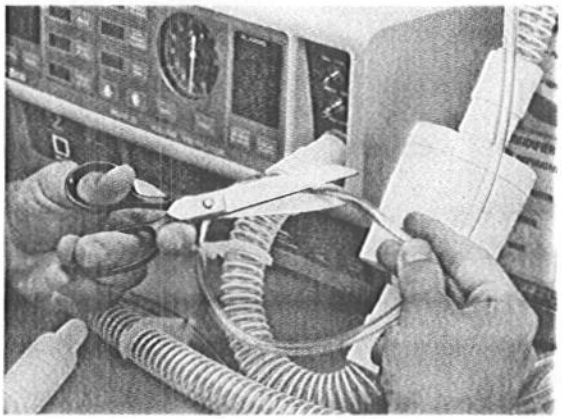
17. Attach the desired number of tubing clips to the 5' patient tubing.



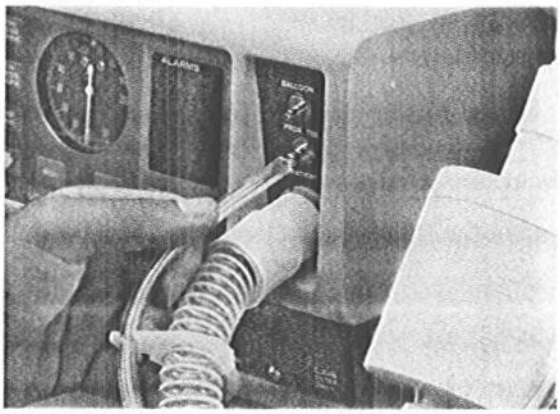
18. Attach the 3/16" proximal pressure sensing line to the 5' patient tubing and the two 9" bacteria filter tubings by snapping it into the tubing clips. Begin at the proximal pressure tee with an extra loop of tubing (as shown in the photo).

WARNING

Do not kink the proximal pressure sensing line. Kinking may result in ventilator malfunction and possible injury.



19. Trim off any excess 3/16" tubing before attaching it to the ventilator. Do not trim the tubing too short.



20. Connect the 3/16" proximal pressure sensing line to the 3/16" barb fitting labelled "PROX. TEE" on the front of the ventilator.

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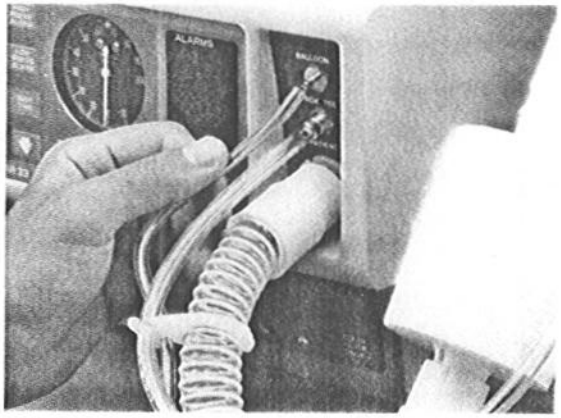
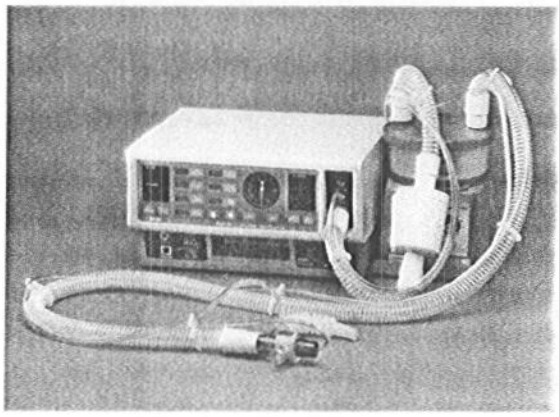
21. Repeat Steps 19 and 20 for the 1/8" exhalation balloon drive line. Begin at the patient manifold.

WARNING

Do not kink the exhalation balloon drive line. Kinking may result in ventilator malfunction and possible injury.



22. Connect the 1/8" exhalation balloon drive line to the 1/8" barb fitting labelled "BALLOON" on the front of the ventilator.



COMPLETE SET-UP OF THE BEAR® 33 VOLUME VENTILATOR WITH AN LS 420 HUMIDIFIER AND APPROPRIATE PATIENT CIRCUIT.

Figure 16

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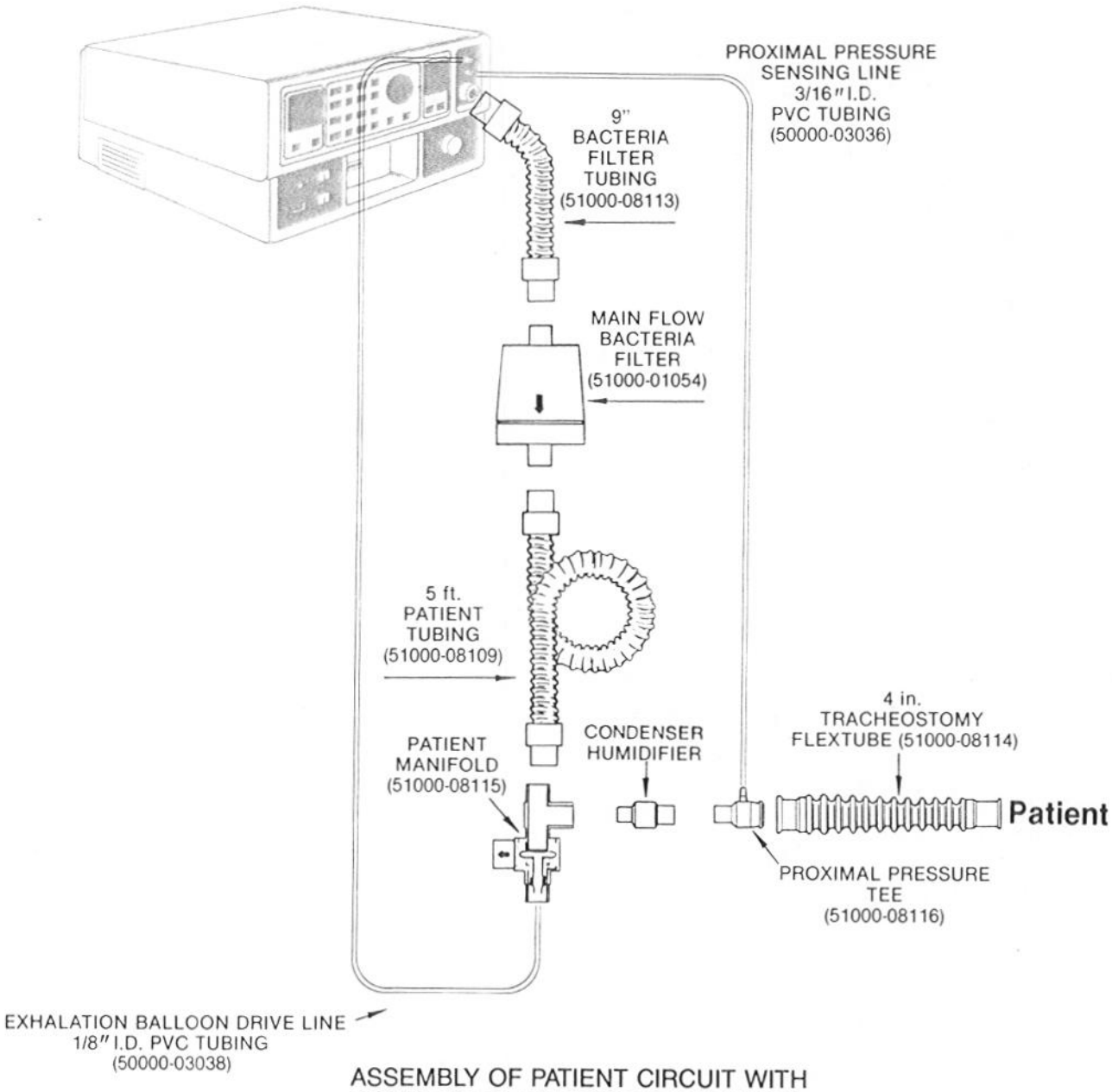


ASSEMBLY OF PATIENT CIRCUIT WITH CONDENSER HUMIDIFIER (ARTIFICIAL NOSE) AND MAIN FLOW BACTERIA FILTER

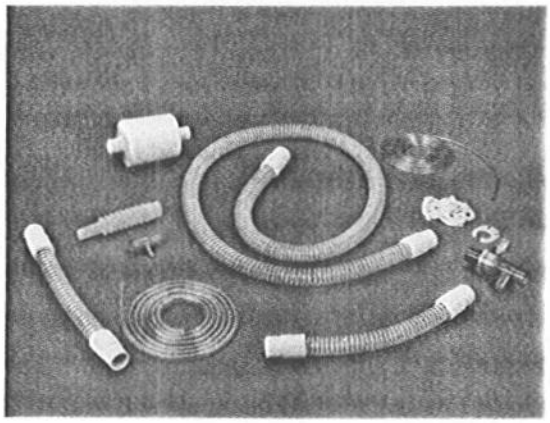
Figure 17

ASSEMBLY OF PATIENT CIRCUIT WITH CONDENSER HUMIDIFIER (ARTIFICIAL NOSE) AND MAIN FLOW BACTERIA FILTER

Accessories needed:

Patient Circuit Kit	(51000-08020)
Main Flow Bacteria Filter Kit	(51000-08104)
Condenser Humidifier	(Artificial nose)

Refer to Figure 17.



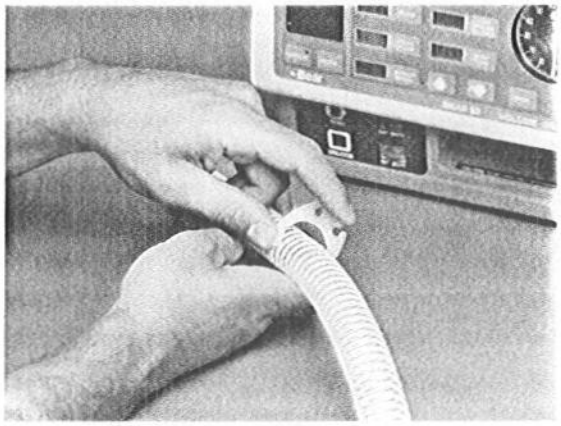
1. Lay out the following kit components:

Patient Circuit Kit*
5′ Patient tubing
8′1/8″ I.D. PVC tubing
8′3/16″ I.D. PVC tubing
Proximal pressure tee
Patient manifold
4″ Tracheostomy flextube
Tubing clips (10 pack)

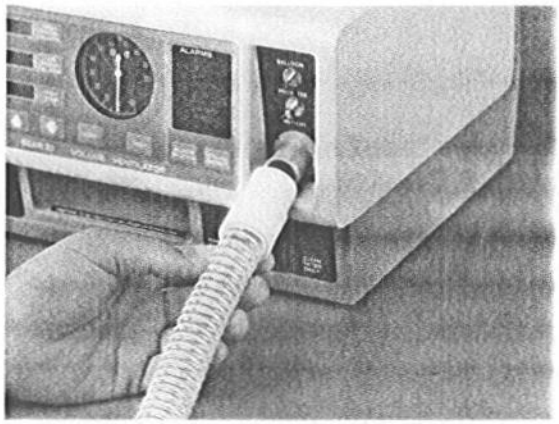
*NOTE: The 18″ humidifier tubing packaged in this kit will not be used.

Main Flow Bacteria Filter Kit*
9″ Bacteria filter tubing (2 ea.)
Main flow bacteria filter

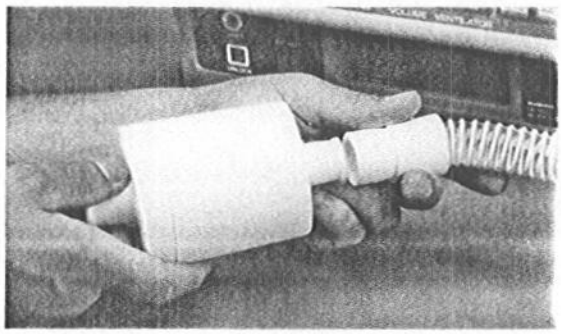
*NOTE: One of the 9″ bacteria filter tubing packaged in this kit will hot be used.



2. Attach one (1) tubing clip to the 9″ bacteria filter tubing.

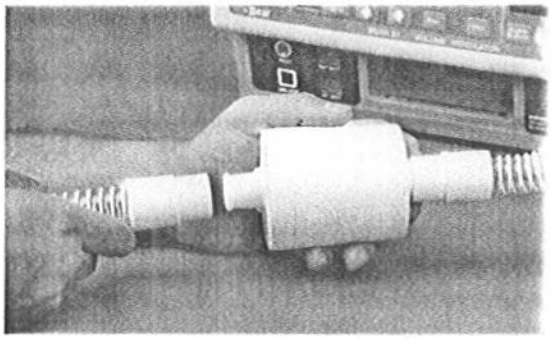


3. Fit the 9″ bacteria filter tubing over the 22 mm output connector labelled "PATIENT" on the front of the ventilator.

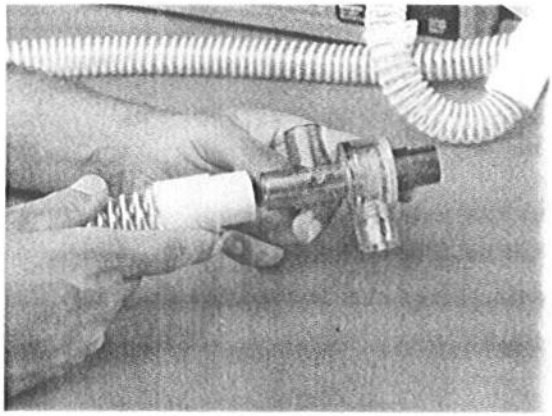


4. Attach the main flow bacteria filter to the free end of the 9″ tubing. Observe the flow direction indicated on the filter.

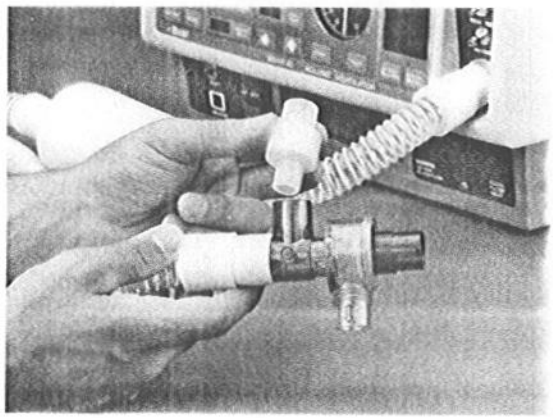
54



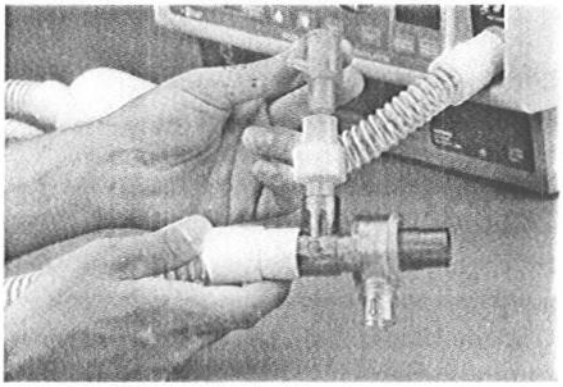
5. Attach the 5′ patient tubing to the free end of the main flow bacteria filter.



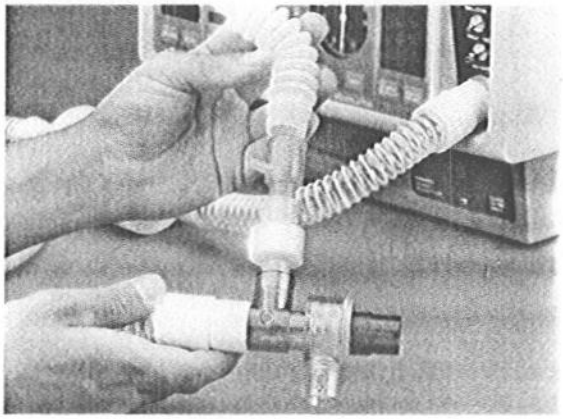
6. Connect the appropriate end of the patient manifold to the free end of the 5′ patient tubing.



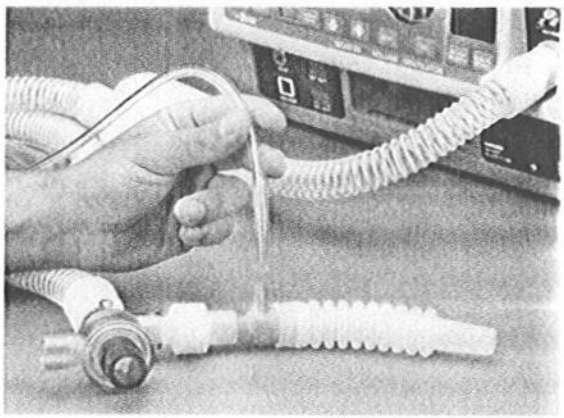
7. Connect the condenser humidifier to the appropriate port on the patient manifold.



8. Connect the proximal pressure tee to the free end of the condenser humidifier.

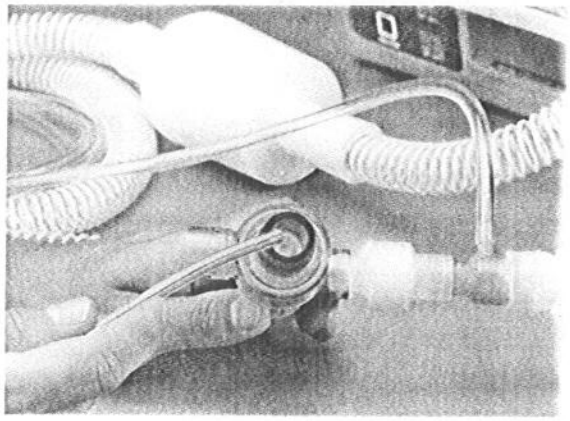


9. Connect the large end of the 4″ flextube to the free end of the proximal pressure tee.

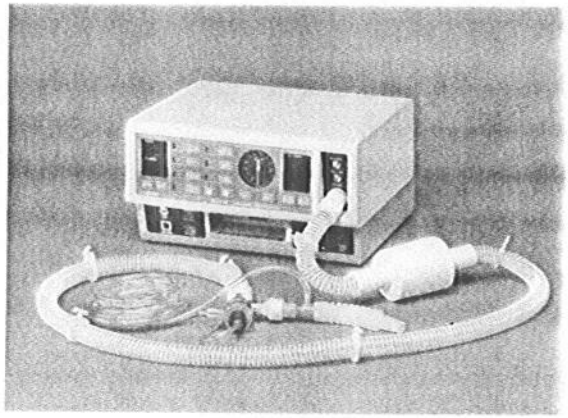


10. Connect one end of the $\frac{3}{16}$″ I.D. PVC tubing (proximal pressure sensing line) to the single port on the proximal pressure tee.

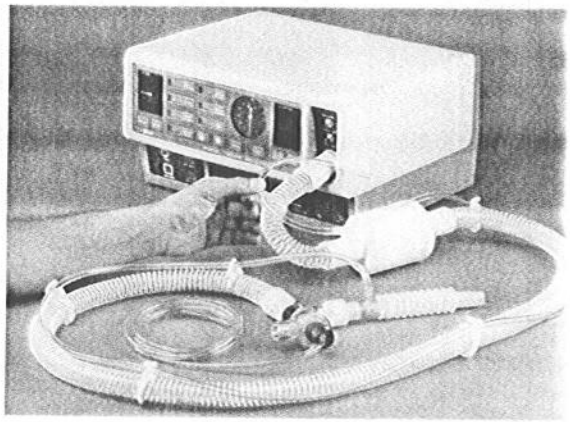
55



11. Connect the 1/8" I.D. PVC tubing (exhalation balloon drive line) to the exhalation balloon port on the patient manifold.



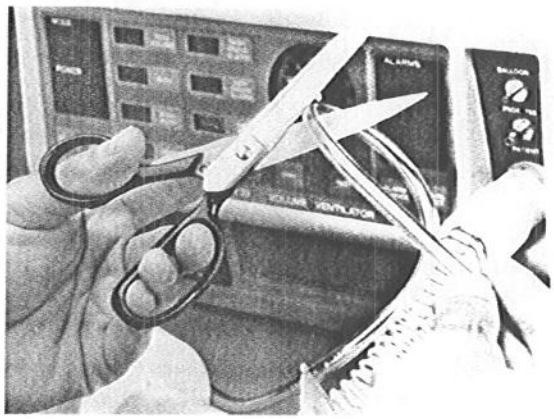
12. Attach the desired number of tubing clips to the 5′ patient tubing.



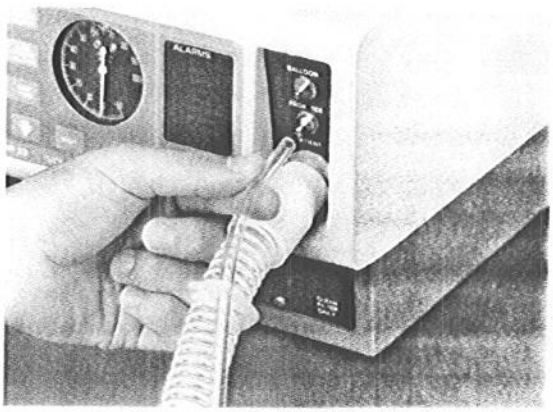
13. Attach the 3/16" proximal pressure sensing line to the 5′ patient tubing and the two 9" bacteria filter tubings by snapping it into the tubing clips. Begin at the proximal pressure tee with an extra loop of tubing (as shown in the photo).

WARNING

Do not kink the proximal pressure sensing line. Kinking may result in ventilator malfunction and possible injury.



14. Trim off any excess 3/16" tubing before attaching it to the ventilator. Do not trim the tubing too short.



15. Connect the 3/16" proximal pressure sensing line to the 3/16" barb fitting labelled "PROX. TEE" on the front of the ventilator.

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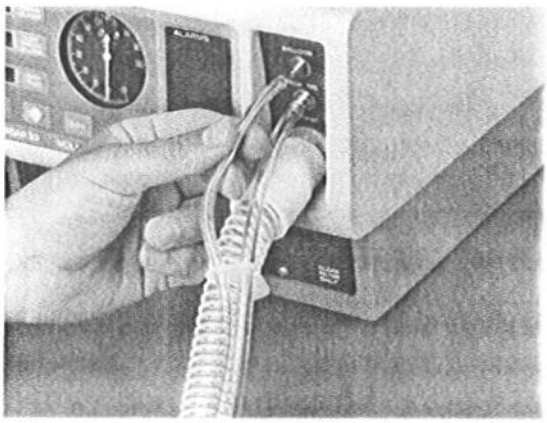
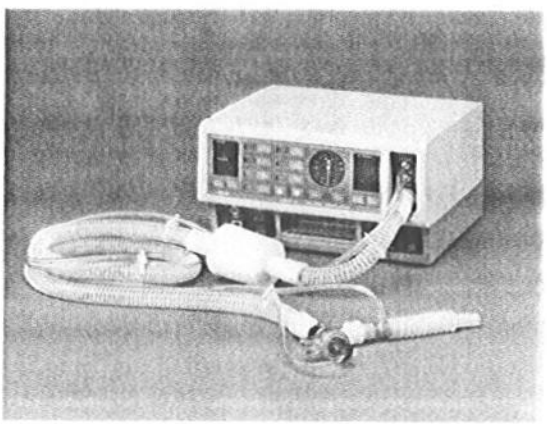
16. Repeat Steps 13 and 14 for the 1/8" exhalation balloon drive line. Begin at the patient manifold.

WARNING

Do not kink the exhalation balloon drive line. Kinking may result in ventilator malfunction and possible injury.



17. Connect the 1/8" exhalation balloon drive line to the 1/8" barb fitting labelled "BALLOON" on the front of the ventilator.



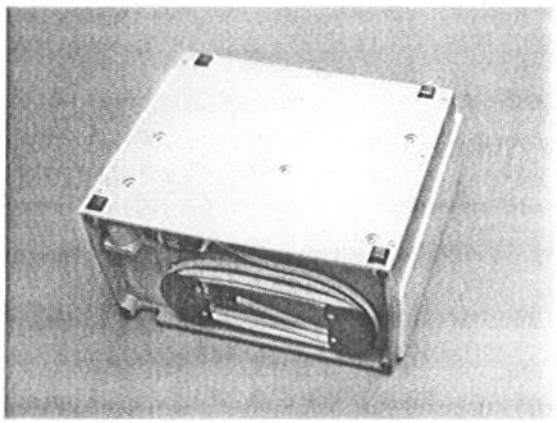
COMPLETE SET-UP OF THE BEAR® 33 VOLUME VENTILATOR WITH CONDENSER HUMIDIFIER, BACTERIA FILTER AND APPROPRIATE CIRCUIT.

Figure 18

MOUNTING THE HUMIDIFIER TO THE VENTILATOR

Accessories needed:

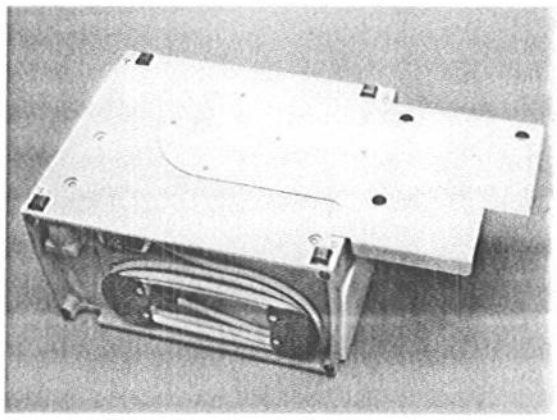
Adult Humidifier	(50000-00420)
or	
Infant Humidifier	(50000-00460)
Humidifier Bracket, Table Mount	(51000-08124)



1. Place the BEAR® 33 Volume Ventilator upside-down on a flat, stable surface.

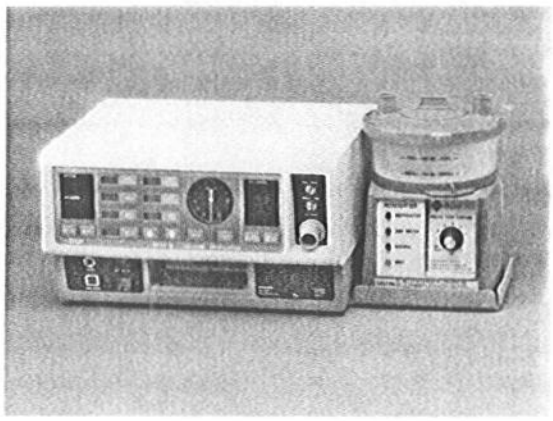
NOTE

The slide mount packaged with the LS 420/460 will not be used.



2. Attach the Table Mount Humidifier Bracket to the bottom surface of the ventilator with the five (5) screws provided. Do not overtighten the screws.

57



3. Place the ventilator in its upright position and set the humidifier control module onto the table mount bracket, making sure the control module feet slip into the bracket.

WARNING

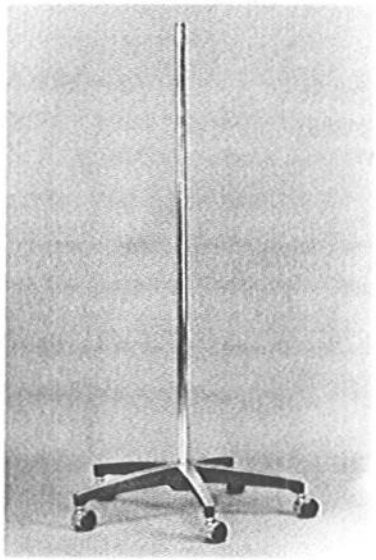
Always mount the humidifier below the level of the patient and drape the patient circuit so that condensate does not drain toward the patient. Frequently drain condensate from the delivery tubes to avoid possible tubing occlusion and discomfort to the patient.

CAUTION

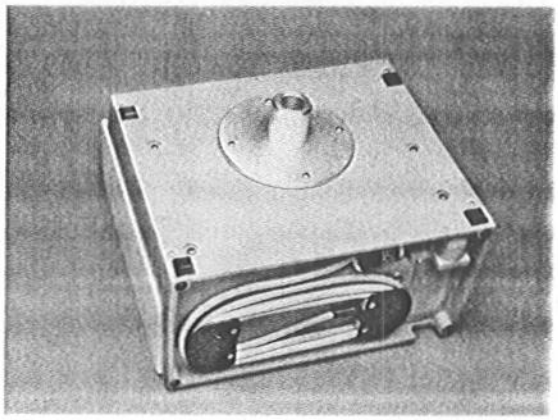
Do not use the humidifier with a patient until proper operation has been verified.

MOUNTING THE VENTILATOR ON THE POLE MOUNT

Accessories needed:
Ventilator Pole Mount (51000-08141)



1. Install the 44″ pole into the wheel base and tighten the two (2) thumbscrews to secure the pole.



2. Install the pedestal mount to the bottom of the ventilator with the four (4) screws provided. Note: Do not overtighten or apply excessive force during installation.

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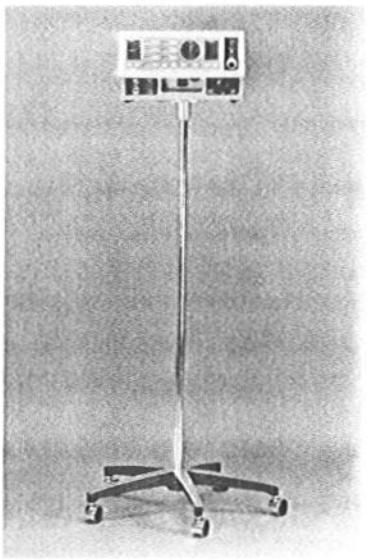
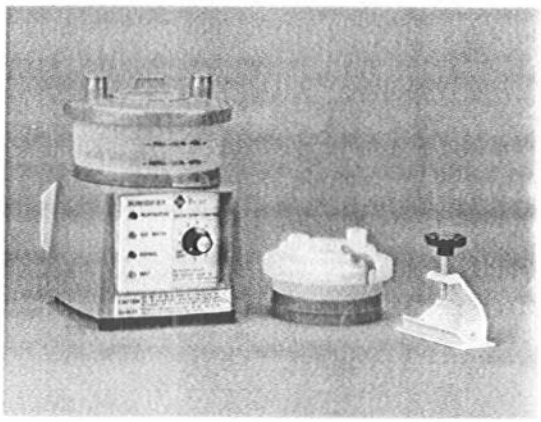
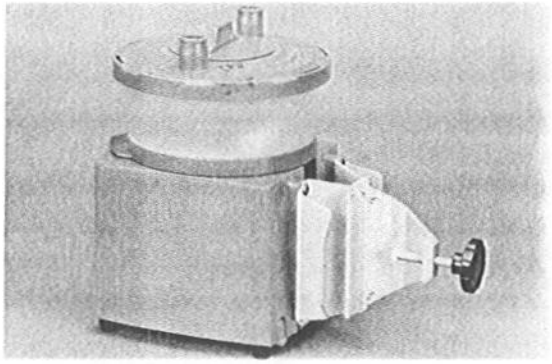


3. Place the BEAR® 33 Volume Ventilator on top of the pole.

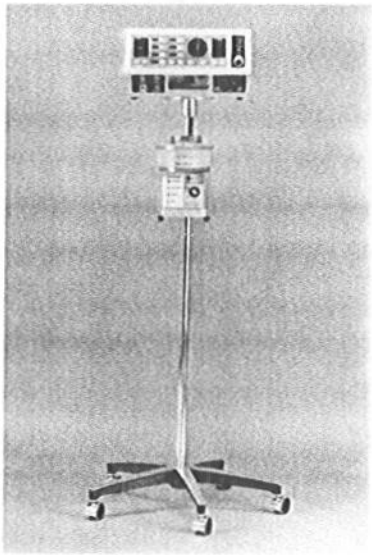
MOUNTING THE HUMIDIFIER ON THE POLE MOUNT

Accessories needed:
Ventilator Pole Mount (51000-08141)





1. Install the Humidifier Pole Mount Assembly (packaged with the humidifier) to the slide mount assembly (already attached to the back of the humidifier) with the two (2) screws provided.



2. Attach the assembled humidifier control module to the ventilator pedestal.

3. For LS 420/460 assembly instructions, refer to the Humidifier Instructions Manual (50000-10420).

WARNING

Always mount the humidifier below the level of the patient and drape the patient circuit so that condensate does not drain toward the patient. Frequently drain condensate from the delivery tubes to avoid possible tubing occlusion and discomfort to the patient.

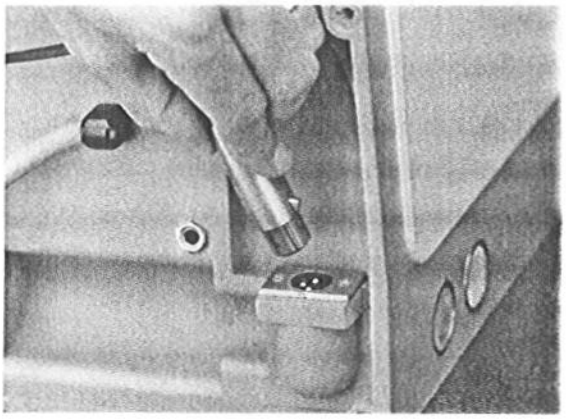
CAUTION

Do not use the humidifier with a patient until proper operation has been verified.

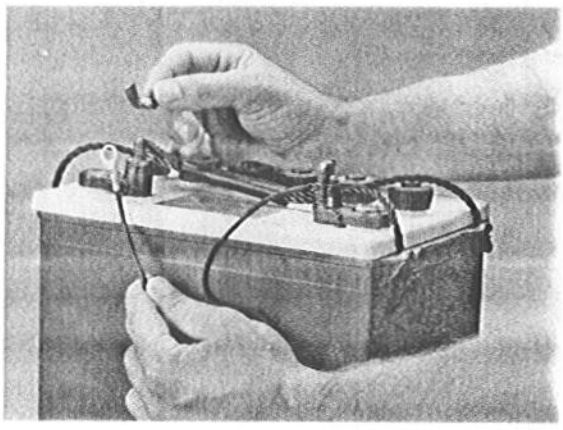
CONNECTING THE EXTERNAL DC BATTERY

Accessories needed:
External Battery Cable (51000-08127)

If AC wall power is not available, the BEAR® 33 Volume Ventilator can be connected to an external 12 VDC battery using the External Battery Cable.



1. The battery cable connects to the rear of the ventilator.



2. The external battery is then connected by hooking up the negative and positive cable connectors to the battery.

Once connected and the unit is turned on, the EXT BATT indicator will illuminate on the front panel if the AC wall power is not connected.

CAUTION

If the negative and positive connectors are reversed during hookup, no power connection will be noted. Always check the EXT BATT indicator and EXT BATT charge status meter to be sure proper connection has been made.

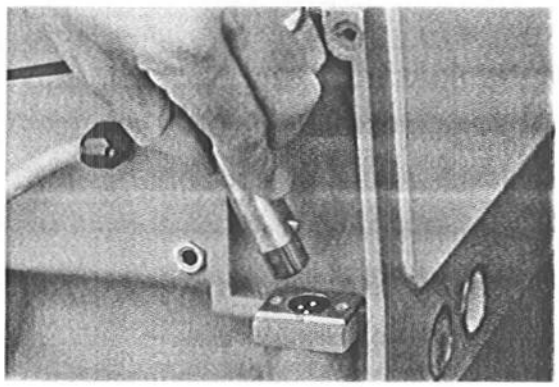
WARNING

Batteries represent explosive hazards. Observe all manufacturer's warnings concerning: placement, handling, connection and ventilation of external 12 VDC batteries.

CONNECTING TO AN AUTOMOBILE EXTERNAL BATTERY

Accessories needed:
External Battery Cable with Automobile Lighter Adapter (51000-08129)

It is possible to power the BEAR® 33 Volume Ventilator with an automobile battery through the cigarette lighter. To make this connection, use the External Battery Cable, Automobile Lighter Adapter.



1. The battery cable connects to the rear of the ventilator.

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2. The lighter adapter is then inserted into the automobile cigarette lighter outlet.

Once connected, the EXT BATT indicator will illuminate on the front panel.

CAUTION

The BEAR® 33 Volume Ventilator is designed to be powered by an external 12V battery. To operate with an automobile battery, the automobile MUST be a 12V system with a negative ground. A 6V car system will not operate the ventilator. Make sure the car system is 12V before attempting external battery operation with the auto adapter.

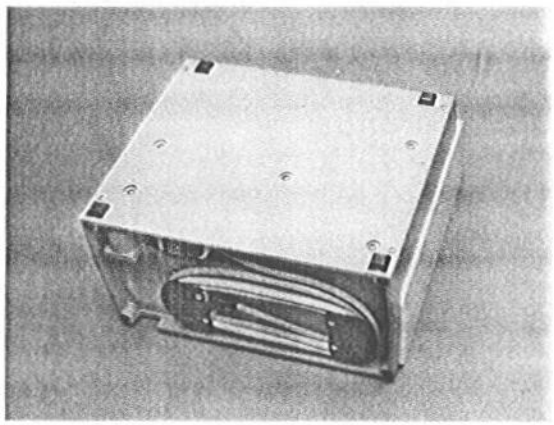
CONNECTING THE OXYGEN ACCUMULATOR

Accessories needed:

Oxygen Accumulator	(51000-08143)
One-Way Valve	(51000-08118)
Oxygen Analyzer	
Source of Oxygen with Flowmeter	
5/32″ I.D. Oxygen Tubing or PVC	

1. Layout the following components:

   Oxygen accumulator
   Adapter (not shown in photo)
   9″ Oxygen accumulator tube
   One-way valve
   Oxygen analyzer
   ¼″ Oxygen tubing



2. Place the BEAR® 33 Volume Ventilator upside-down on a flat, stable surface.

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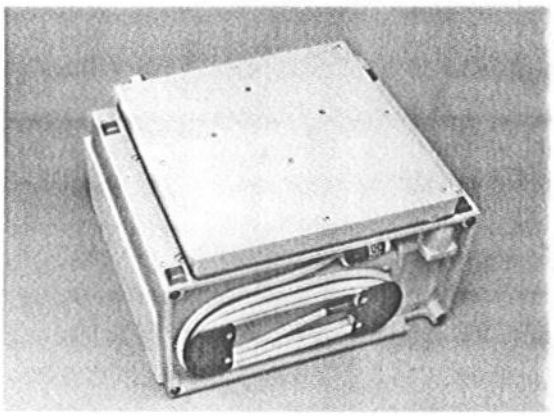
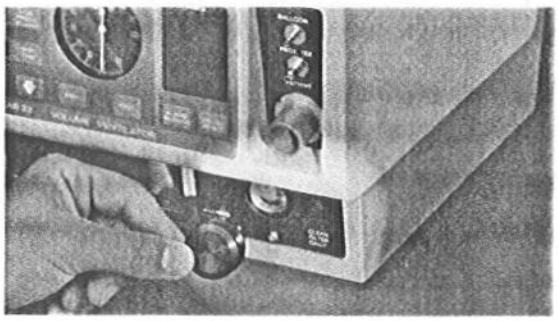
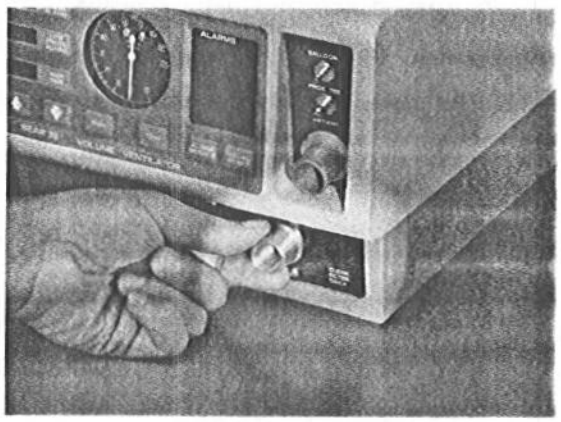


3. Attach the Oxygen Accumulator to the bottom surface of the ventilator with the four (4) screws and washers provided. Note: Do not apply excessive force or overtighten.

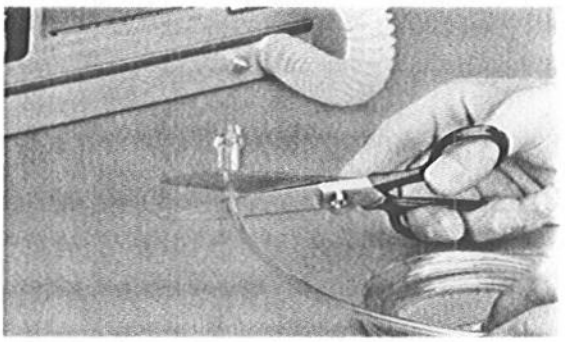


4. Unscrew the round inlet cover (counter-clockwise) from the GAS INLET door on the lower right corner of the front panel.

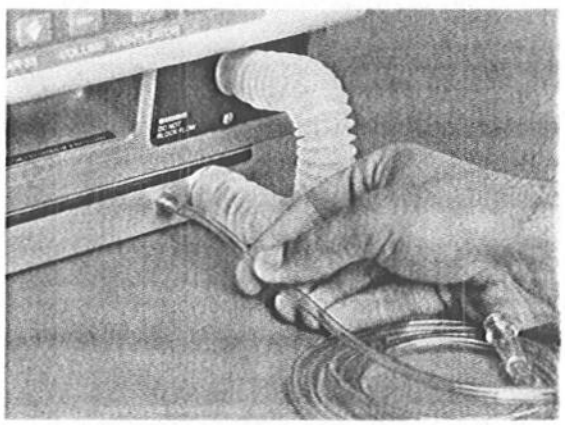


5. Screw the 27 mm adapter provided with the accumulator assembly into the GAS INLET door.

6. Connect the output of the accumulator to the 27 mm adapter with the 9″ oxygen accumulator tube.



7. Trim off one end of the 5/32″ oxygen tubing.



8. Connect the 5/32″ oxygen tubing to the oxygen inlet fitting of the accumulator. To determine oxygen input flow rate, see the O_2 accumulator chart in the Theory of Operation Section.

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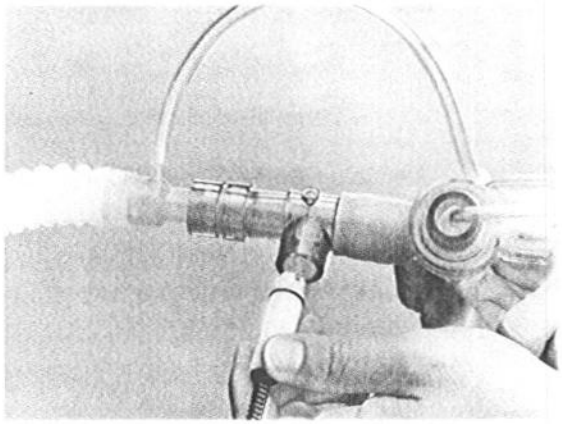
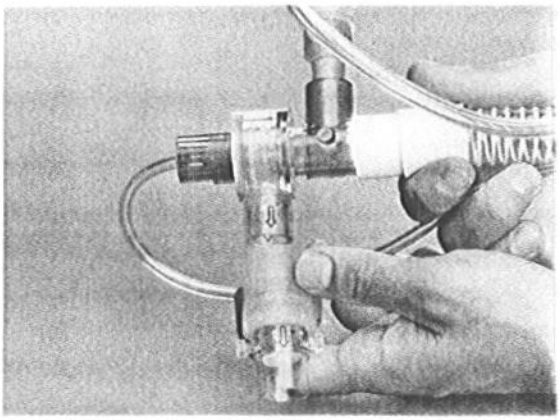


9. Connect the Oxygen Analyzer (per manufacturer's instructions) between the patient manifold and the proximal pressure tee.

NOTE

This setup will measure patient FIO_2 when the patient's inspiration is coming from both the ventilator and the exhalation valve (without the use of a one-way valve).



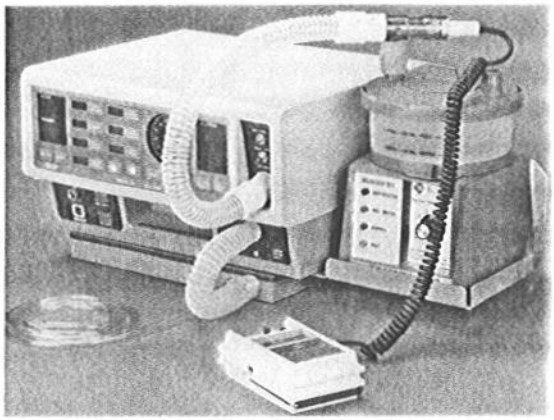
10. Attach the one-way valve to the exhalation port of the patient manifold.

WARNING

Misplacement of the one-way valve will not allow the patient to exhale. Observe the direction of the arrow and confirm the ability to exhale.

NOTE

If using a one-way valve on the exhalation port of the patient manifold, you may place the O_2 analyzer in the 18″ humidifier circuit between the ventilator output and the humidifier inlet port.



WARNING

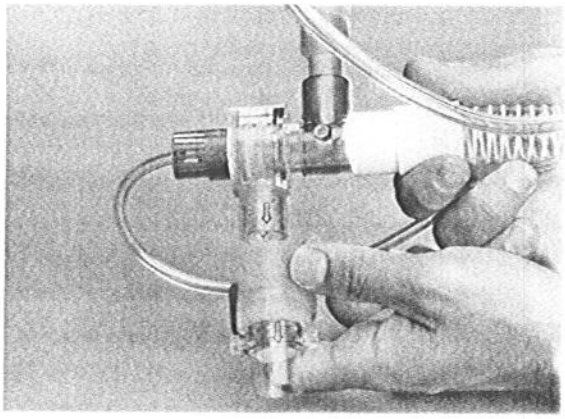
Consult a physician on proper fractional concentration of inspired oxygen (FIO_2). Monitor oxygen concentrations at or near the proximal airway (when using a one-way valve) with an oxygen analyzer.

CONNECTING THE ONE-WAY VALVE

Application of the one-way valve will not allow air to be inhaled past the exhalation balloon. This enhances the sensitivity of the BEAR® 33 Volume Ventilator to patient efforts when ventilating in the ASSIST control and SIMV modes.

Accessories needed:

One-Way Valve	(51000-08118)



1. Connect the One-Way Valve to the exhalation port.

NOTE

Some manifolds may not require the rubber connector.

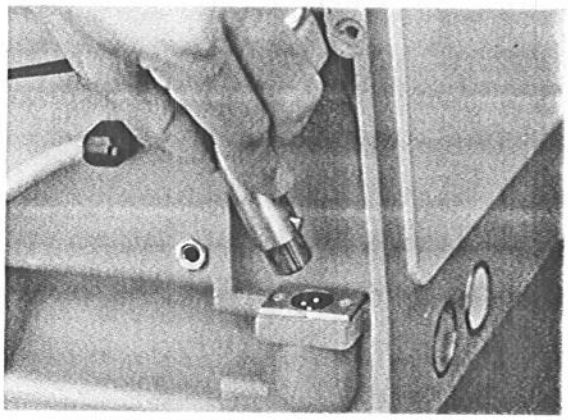
WARNING

Misplacement of the one-way valve will not allow the patient to exhale. Observe the direction of the arrow and confirm the ability to exhale.

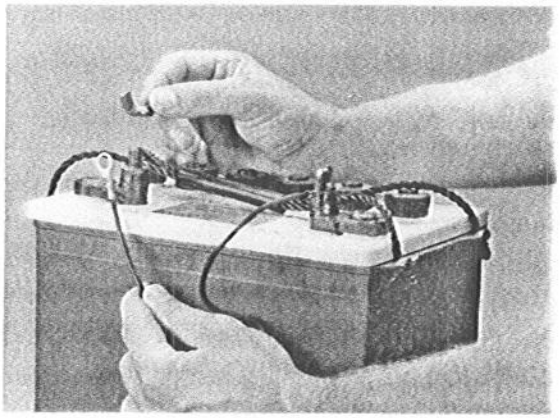
MOUNTING THE VENTILATOR ON A WHEELCHAIR

Accessories needed:
External Battery Cable (51000-08127)

The BEAR® 33 Volume Ventilator is designed to be mounted on to a wheelchair.



1. Connect the external DC battery to the rear of the ventilator.



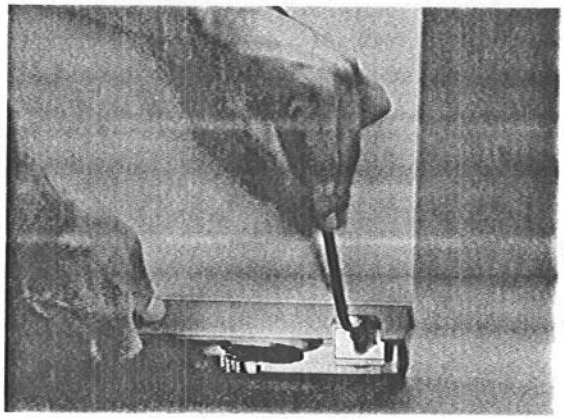
2. Connect the cable to the external battery by attaching the negative and positive cable connectors to the appropriate terminals.

CAUTION

If the negative and positive connectors are reversed during hookup, no power connection will be noted. Always check the EXT BATT indicator and EXT BATT charge status meter to be sure proper connection has been made.

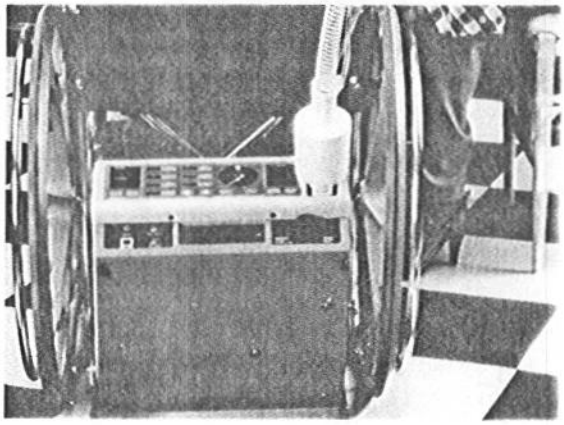
WARNING

Batteries represent explosive hazards. Observe all manufacturer's warnings concerning: placement, handling, connection and ventilation of external 12 VDC batteries.



3. Turn the ventilator on to its rear panel, making sure the cable is located in

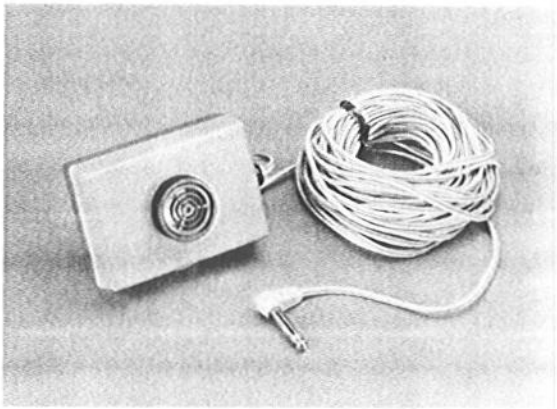
the panel notch. This will provide stability of the ventilator on the wheelchair.



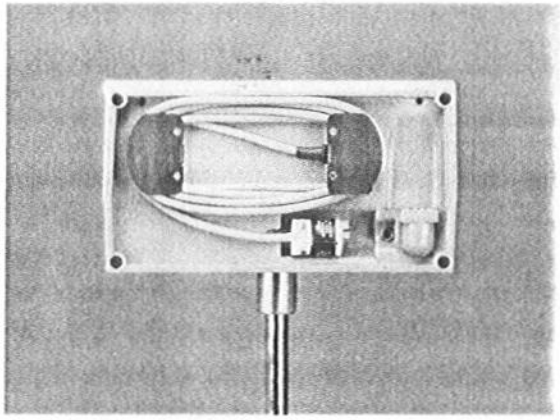
4. Set the ventilator on the wheelchair. Be sure not to occlude the case vent filter located on the side panel.

CONNECTING THE REMOTE ALARM

Accessories needed:
Remote Alarm (51000-08131)



1. Connect the male jack to the back of the BEAR® 33 Volume Ventilator.



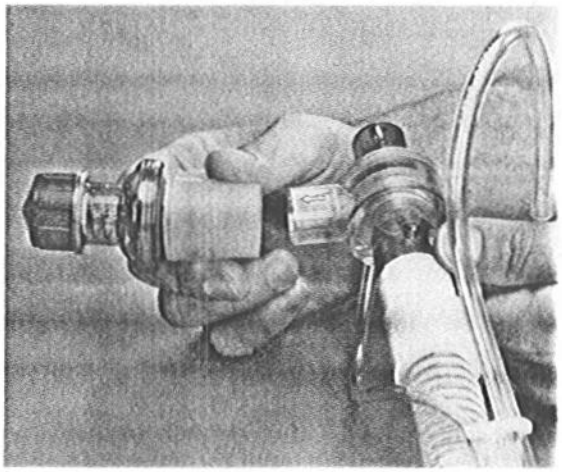
2. Move the alarm body to the desired room, up to 40 feet away.

CONNECTING THE PEEP VALVE

When used, this valve allows a positive end expiratory pressure to be maintained in the patient circuit. Application of the PEEP valve will not allow air to be inhaled past the exhalation balloon, and may result in increased work of breathing as well as some Tidal Volume loss. See the Theory of Operation section for more detail.

Accessories needed:

PEEP VALVE (0-20 cmH_2O) 51000-08117



1. Connect the PEEP Valve to the Exhalation Port.

NOTE

Some manifolds will not require the rubber connector.

2. Select the desired level of PEEP.
3. Adjust the Sensitivity control to the desired level.
4. Adjust the Low Pressure Alarm to the desired level.

WARNING

The ASSIST SENSITIVITY control must be properly adjusted in the SIMV Mode to insure accurate monitoring of spontaneous breaths. It is necessary to properly set the ASSIST SENSITIVITY control in the SIMV mode to synchronize patient effort with ASSISTED and CONTROLLED breaths. Improper adjustment could lead to stacking CONTROLLED breaths on top of the patient's spontaneous breaths (if the sensitivity control is set higher than actual patient effort).

WARNING

ASSIST SENSITIVITY must be set below patient baseline pressure in ASSIST CONTROL and SIMV modes to prevent autocycling.

WARNING

Use of PEEP may lead to increased work of breathing in some patients, resulting in rebreathing and CO_2 retention. Evaluate the patient's ability to perform the work of breathing when PEEP is used. The PEEP Valve generates an end expiratory pressure only, and does not maintain CPAP (constant positive airway pressure) during a spontaneous breath.

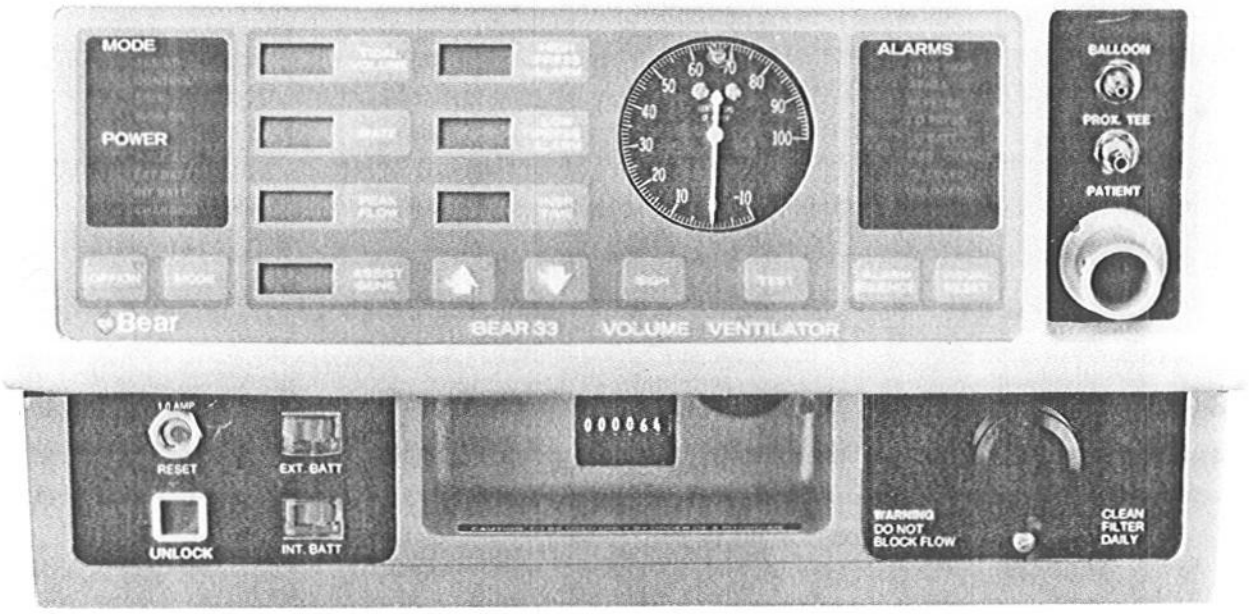
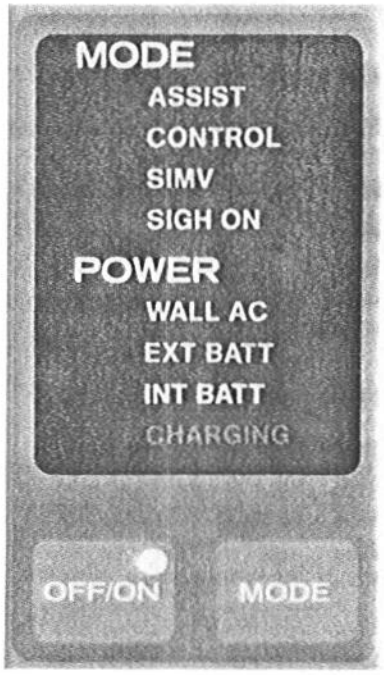
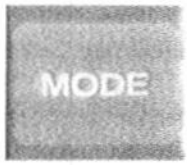

MODE
POWER
ALARMS
BALLOON
PROX. TEE
PATIENT
Bear
BEAR 33 VOLUME VENTILATOR
1.0 AMP
RESET
EXT. BATT
UNLOCK
INT. BATT
000064
WARNING
DO NOT
BLOCK FLOW
CLEAN
FILTER
DAILY

Figure 19



Refer to Figure 19 to determine the approximate location of the ventilator controls, indicators and displays.



MODE

The MODE button selects one of three available modes: CONTROL, ASSIST CONTROL and SIMV.

Each time the MODE button is depressed, one of three indicators will illuminate to identify the operating mode.

To select the desired mode, depress this button the necessary number of times to illuminate the appropriate indicator.

ASSIST CONTROL

In the ASSIST CONTROL mode, a positive pressure breath is triggered when the patient's spontaneous inspiratory effort drops below the pre-set ASSIST SENSITIVITY level as determined by the ASSIST SENSITIVITY control setting. If the patient does not trigger the machine within the breath-to-breath time interval as set by the RATE control, the ventilator will automatically deliver a controlled breath. The TIDAL VOLUME and INSPIRATORY TIME of the assisted breath are the same as a controlled breath.

Assisted breaths can occur at rates exceeding the RATE control setting; however, 750 msec. must elapse at the end of inspiration before the ventilator will deliver the next assisted breath.

The ASSIST portion of the ASSIST CONTROL indicator will blink off momentarily when an assisted breath is being delivered. The capital letter "A" will also flash on the assist sensitivity display.

NOTE

To insure proper sensitivity of the ASSIST SENSITIVITY detector, a one-way valve may be used on the exhalation port of the patient manifold.

WARNING

ASSIST SENSITIVITY must be set below patient baseline pressure in ASSIST CONTROL and SIMV modes to prevent autocycling.

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CONTROL

CONTROL

The ventilator delivers gas to the patient at the selected TIDAL VOLUME, PEAK FLOW and RATE settings. In the CONTROL Mode, the ASSIST SENSITIVITY display will show the last keyed-in setting; however, it is not operational.

NOTE

The patient may still draw spontaneous breaths in the CONTROL mode through the piston bypass check valve.

SIMV

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION

Allows the patient to breathe spontaneously and to receive a fixed number of positive pressure breaths as set by the RATE control. The positive pressure breaths may be patient initiated (assisted) or ventilator initiated (controlled) as in the ASSIST CONTROL mode. The patient initiated positive pressure breaths are synchronized with the patient's breathing pattern, but limited to the rate set by the RATE control.

NOTE

To insure proper sensitivity of the ASSIST SENSITIVITY detector, a one-way valve may be used on the exhalation port of the patient manifold.

The breath-to-breath interval determined by the RATE control becomes an "Assist Window" generated by the ventilator. An assisted breath closes the assist window for that time interval. If no assisted breath occurs, the assist window remains open until an assisted breath occurs and controlled breaths are delivered at a normal rate.

When the assist window is open, the patient can take shallow spontaneous breaths at pressure levels insufficient to trigger an assisted breath. The patient can breathe spontaneously at any flow level when the assist window is closed. The assist window will not open for 750 msec. following a spontaneous breath which triggers the ASSIST SENSITIVITY (effort) detector or for 750 msec. after a control breath.

WARNING

The ASSIST SENSITIVITY control must be properly adjusted in the SIMV mode to insure accurate monitoring of spontaneous breaths. It is necessary to properly set the ASSIST SENSITIVITY control in the SIMV mode to synchronize patient effort with ASSISTED and CONTROLLED breaths. Improper adjustment could lead to stacking CONTROLLED breaths on top of the patient's spontaneous breaths (if the sensitivity control is set higher than actual patient effort).

SIGH ON

SIGH ON

Indicates the SIGH function is on. This indicator blinks on and off during a SIGH breath delivery.

POWER OFF/ON

The OFF/ON button controls power to the ventilator. When the unit is off, a single depression of the button will turn the ventilator on, verified by a green indicator light.

When the unit is on, the OFF/ON button is normally locked in the ON position. To turn the unit off, depress the UNLOCK button first, then depress the OFF/ON button.

WALL AC

WALL AC

This indicator will illuminate green whenever the AC power cord is plugged into an active AC power source and the power button is ON.

EXT BATT

EXT BATT

This indicator will illuminate green when the ventilator is operating from an external battery power source.

NOTE

The external and internal batteries are being charged as long as the ventilator is plugged into an active AC power source. The "charging" indicator will remain on while the unit is plugged into wall AC.

INT BATT

INT BATT

This indicator will illuminate yellow when the ventilator is operating from the internal battery.

WARNING

A fully charged internal battery provides approximately one hour of ventilator operating time. This battery is a backup source of power for use during emergencies and transitions between other power source changes. The patient should not be left unattended at any time during use of the internal battery and an alternative power source should be connected immediately.

AUTOMATIC SELECTION OF POWER SOURCE

The ventilator automatically selects the highest level power source available:

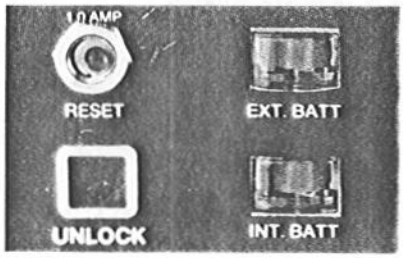
AC Wall Power — Always used when the ventilator is connected to an active AC power source.

External Battery — If wall AC power is not available, the ventilator automatically switches to an external battery power source, if connected.

Internal Battery — The ventilator will automatically switch to the internal battery power source when there is no AC wall power, no external battery is connected to the unit or the external battery charge is low.

CHARGING

This indicator will illuminate green when the unit is plugged into an active AC power source, indicating the battery/batteries is/are charging.



CIRCUIT BREAKER

The circuit breaker protects the electronic circuitry and the motor drive from current overload.

When the circuit breaker trips, its center button will pop out. To reset, press in the button.

WARNING

DO NOT reset the circuit breaker more than once. If the circuit breaker trips after resetting, the ventilator should be turned OFF and the unit referred to an authorized service technician.

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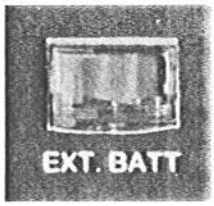
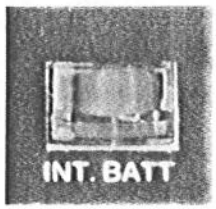


EXTERNAL BATTERY CHARGE METER

A visual indication of the approximate external battery charge available. The GREEN area indicates an adequate charge while the RED area indicates an unacceptable charge and may be accompanied by a PWR CHANGE alarm. When the indicator is in the RED area, plug the unit into an AC outlet immediately.

NOTE

Check the battery charge level with the AC power disconnected, and the unit running, since the battery meter indicates the charging process.



INTERNAL BATTERY CHARGE METER

A visual indication of the approximate (percentage) internal battery charge available. When the indicator is to the far right of the GREEN area, approximately 1 hour of power exists. The RED area indicates an unacceptable charge and may be accompanied by a LOW BATT alarm. When the indicator is in the RED area, plug the unit into an AC outlet immediately.

NOTE

Check battery charge level with AC power disconnected, and the unit running, since the battery meter indicates the charging process.

PANEL LOCK

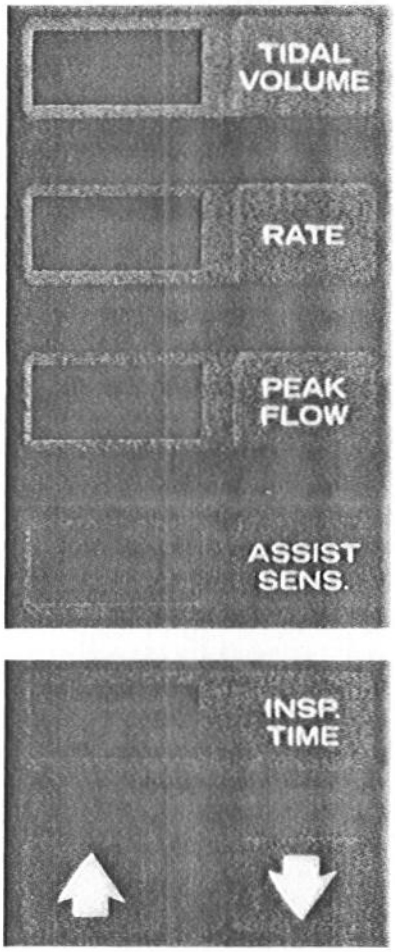
Depressing this button allows access to the following controls:

- OFF/ON (OFF ONLY)
- MODE
- TIDAL VOLUME
- RATE
- PEAK FLOW
- ASSIST SENSITIVITY
- HIGH PRESSURE
- LOW PRESSURE
- UP
- DOWN
- SIGH

The listed controls will remain active for 15 seconds from the last key stroke on any of these buttons. If no button is pressed for 15 seconds, the panel will automatically lock all buttons until UNLOCK is depressed again.

NOTE

To lock the panel at any time during the 15 second window, depress the UNLOCK button.



TIDAL VOLUME

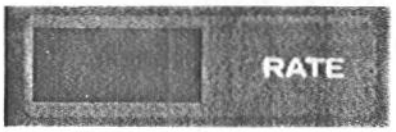
Adjustable from 100 cc to 2200 cc in increments of 10 cc. This control sets the volume of the positive pressure breaths to be delivered to the patient.

To adjust, depress the button to the right of the display and simultaneously depress the UP/DOWN buttons to change the setting.

NOTE

When the minimum or maximum TIDAL VOLUME specification range limit is reached, the display will stop changing and flash for as long as it is requested to exceed its upper or lower limit. Once the UP or DOWN button or TIDAL VOLUME button is released, the display will stop flashing (see Table 4).

The TIDAL VOLUME display is also used to display error codes. The error code will appear as "E" followed by a number 01 to 13, i.e. (E02). Error codes will only appear in the TIDAL VOLUME display when the unit is in a VENT INOP condition. For further information see the Theory of Operation section on ERROR Codes.



RATE

Adjustable from 2.0 BPM to 40 BPM. Adjustable in increments of 0.5 BPM from 2.0 BPM to 10 BPM and increments of 1 BPM from 10 BPM to 40 BPM. This control determines the number of positive pressure breaths delivered by the ventilator in the CONTROL and SIMV modes and the minimum number of breaths delivered in the ASSIST CONTROL mode.

NOTE

When the maximum or minimum RATE specification range limit is reached, the display will stop changing and flash for as long as it is requested to exceed its upper or lower limit. Once the UP or DOWN button or RATE button is released, the display will stop flashing (see Table 4).

PEAK FLOW

Adjustable from 20 LPM to 120 LPM in increments of 1 LPM. Controls the PEAK FLOW rate of ventilator delivered positive pressure breaths. This control does not affect spontaneous inspiratory flow rate.

NOTE

When the maximum or minimum PEAK FLOW specification range limit is reached, the display will stop changing and flash for as long as it is requested to exceed its upper or lower limit. Once the UP or DOWN button or PEAK FLOW button is released, the display will stop flashing (see Table 4).

TABLE 4

DETECTION OF BEAR® 33 VOLUME VENTILATOR OPERATING RANGE LIMITS

PARAMETER BEING ADJUSTED	PARAMETER RANGE LOWER & UPPER LIMITS	FLASHING DISPLAY
TIDAL VOLUME	100 — 2200 cc	TIDAL VOLUME
RATE	2 — 40 BPM	RATE
PEAK FLOW	20 — 120 LPM	PEAK FLOW
ASSIST SENSITIVITY	-9 — 19 cmH_2O	ASSIST SENS

BEAR® 33 VOLUME VENTILATOR SET-UP LIMITATIONS (OPERATING ENVELOPE)

The BEAR® 33 Volume Ventilator has been designed to operate within a predefined set of conditions. This operating envelope insures the user that the ventilator cannot be SET UP in an inverse I:E ratio or outside of the predefined T_I range. The operating settings for TIDAL VOLUME RATE and PEAK FLOW are limited so no combination of these parameters can deliver an I:E ratio less than 1:1.

When setting up the TIDAL VOLUME, RATE and PEAK FLOW controls, their individual LCD displays may stop changing and begin to flash indicating the parameter cannot be moved any further in that specific direction. The combination of what is already shown on the other two displays and the desired change in the third parameter would cause an inverse I:E ratio condition or violation of the T_I limits.

If the limited parameter will not adjust to the desired setting, one of the other two controls must be changed to allow movement of the third.

INSPIRATORY TIME DISPLAY

The INSPIRATORY TIME display is a function of the TIDAL VOLUME and PEAK FLOW settings. To change T_I, adjust one or both of these parameters.

a. Minimum T_I allowed by the ventilator = 0.25 seconds.

b. Maximum T_I allowed by the ventilator = 4.99 seconds.

c. Minimum T_E = 0.75 seconds in ASSIST CONTROL or SIMV.

NOTE

If the user attempts to set a combination of RATE, TIDAL VOLUME and PEAK FLOW where the T_I rules limit the parameter ranges, the parameter will flash and the INSPIRATORY TIME display will also flash (see Table 5).

The following will always hold true:

1. A flashing T_I display setting of 0.25 in combination with another parameter flashing indicates the limiting factor is minimum T_I.
2. A flashing T_I display setting of 0.26 to 4.98 in combination with another parameter flashing means the 1:1 I:E ratio is the limiting factor.
3. A flashing T_I display setting of 4.99 in combination with another parameter flashing, indicates the limiting factor is maximum T_I.

TABLE 5

DETECTION OF BEAR® 33 VOLUME VENTILATOR FUNCTION CONTROL BOUNDARIES

PARAMETER BEING ADJUSTED	FUNCTIONAL CONTROL BOUNDARY	FLASHING DISPLAYS
TIDAL VOLUME	T_I = 0.25 OR T_I = 4.99 OR I:E RATIO 1:1	TIDAL VOLUME AND INSPIRATORY TIME
RATE	I:E RATIO 1:1	RATE AND INSPIRATORY TIME
PEAK FLOW	T_I = 0.25 OR T_I = 4.99 OR I:E RATIO 1:1	PEAK FLOW AND INSPIRATORY TIME

ASSIST SENSITIVITY

Adjustable from -9 to 19 cmH_2O in increments of 1 cmH_2O. Adjusts the threshold of required patient effort to initiate a machine delivered breath in the ASSIST CONTROL and SIMV modes. The ASSIST SENSITIVITY display setting is an ABSOLUTE pressure level.

When the maximum or minimum ASSIST SENSITIVITY specification range limit available is reached, the display will stop changing and flash for as long as it is requested to exceed its upper or lower limit. Once the UP or DOWN button or ASSIST SENSITIVITY button is released, the display will stop flashing (see Table 4).

When the patient pressure goes below the ASSIST SENSITIVITY setting, the letter "A" will flash on to the left of the ASSIST SENSITIVITY setting.

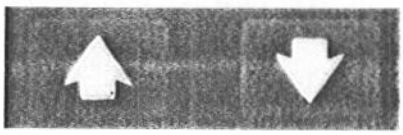
NOTE

To insure proper sensitivity of the ASSIST SENSITIVITY detector, a one-way valve may be used on the exhalation port of the patient manifold.

WARNING

ASSIST SENSITIVITY must be set below patient baseline pressure in ASSIST CONTROL and SIMV modes to prevent autocycling.

The ASSIST SENSITIVITY control must be properly adjusted in the SIMV mode to insure accurate monitoring of spontaneous breaths. It is necessary to properly set the ASSIST SENSITIVITY control in the SIMV mode to synchronize patient effort with ASSISTED and CONTROLLED breaths. Improper adjustment could lead to stacking CONTROLLED breaths on top of the patient's spontaneous breaths (if the sensitivity control is set higher than actual patient effort).



UP/DOWN BUTTONS

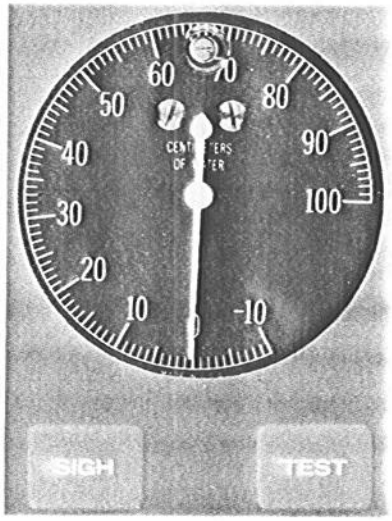
These two buttons allow the operator to increase or decrease the digital display settings of the following:

- TIDAL VOLUME
- RATE
- PEAK FLOW
- ASSIST SENSITIVITY
- HIGH PRESSURE ALARM
- LOW PRESSURE ALARM

To increase or decrease a parameter setting, the parameter is first selected by its individual control button. Then the desired parameter button must be held down while the appropriate UP or DOWN button is depressed. Once the digital display reflects the desired setting, release both buttons. The panel will automatically lock the settings in place 15 seconds from the last key stroke. The breath delivered to the patient at any time is based upon the control settings at the beginning of that breath.

NOTE

To adjust any of the digital displays, the panel must be UNLOCKED.



PROXIMAL AIRWAY PRESSURE GAUGE

Displays the pressure at the proximal airway over the range of -10 to +100 cmH_2O.

TEST

Activates all display segments (except CHARGING), indicators and audible alarms for operator inspection. This process does not affect the on-going delivery of breaths to the patient.

NOTE

To test the integrity of the CHARGING indicator, plug the unit into an active wall outlet.

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SIGH

The SIGH control is an ON/OFF function. In the ON position, sigh will be delivered to the patient under the following criteria:

SIGH VOLUME	= 1.5 x TIDAL VOLUME OR 3300 ml WHICHEVER IS LESS
RATE	= 6 SIGHS/HOUR
HI PRESS ALARM	= 1.5 x PANEL SETTING
SIGH EXPIRATORY TIME	= 1.5 x SIGH INSPIRATORY TIME

NOTE

The HI PRESS ALARM setting is increased by 50% during a SIGH breath; however, this is not indicated on the digital display. To determine if this increase is appropriate, check the pressure manometer reading during a sigh breath. If the peak pressure is more than 1.5 times the peak pressure of a normal breath, adjust the HIGH PRESS ALARM setting accordingly. Expiratory time during a SIGH breath is automatically increased to 1.5 times the SIGH inspiratory time to allow the patient to adequately exhale.

SIGH expiratory time will overflow into the next defined rate window. To prevent mandatory breaths stacking on SIGH breaths, the end of SIGH expiratory time will establish a new rate window.

During controlled SIGH, the patient may not initiate an assisted breath for 750 msec or piston pullback time, whichever is greater.

During assisted (synchronous) SIGH, the patient may not initiate an assisted breath until the end of the defined SIGH expiratory time.

MANUAL SIGH

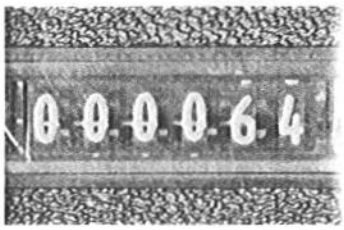
If a MANUAL SIGH is desired, the following must occur:

1. Unlock the panel.
2. Push SIGH button, wait until SIGH occurs (1 or 2 breaths later).
3. Turn SIGH off.

For multiple MANUAL SIGHS, repeat the above sequence.

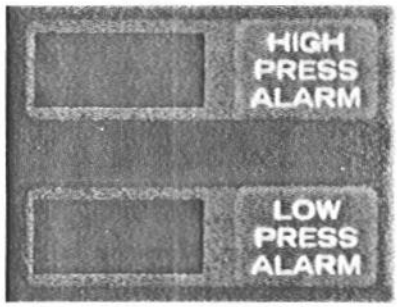
If SIGH function is activated and MANUAL SIGH is desired, the following must occur:

1. Unlock the panel.
2. Push SIGH button, wait until SIGH ON lamp goes out.
3. Push SIGH button, wait until a sigh occurs (1 or 2 breaths later).



HOUR METER

The HOUR METER records the total hours of ventilator operation whenever the ventilator OFF/ON button is on. The meter is non-resettable and allows the clinician to determine the actual usage hours as well as establishing periods of routine maintenance. All new units will show some operation hours due to final calibration and check-out at the factory.



HIGH PRESSURE ALARM AND LIMIT

Adjustable from 10 cmH_2O to 80 cmH_2O in increments of 1 cmH_2O. This control limits the patient pressure in the inspiratory phase.

OPERATION FROM 10-79 cmH_2O

On the first positive pressure breath which exceeds the HIGH PRESSURE ALARM level, the following occurs:

a. The visual indicator, HI PRESS, is illuminated and flashing.

b. Piston forward motion is halted, terminating volume delivery.

c. Pressure Limit Solenoid Valve is opened.

d. Patient Exhalation Balloon pressure is relieved by (c) and patient pressure falls to atmosphere.

If the second positive pressure does not exceed the alarm limit, the visual indicator turns off.

If the second positive pressure breath exceeds the HIGH PRESS ALARM limit, the following occurs:

a. Visual indicator HI PRESS continues to flash.

b. Audible alarm will sound.

c. Piston forward motion is halted, terminating volume delivery.

d. Pressure Limit Solenoid Valve is opened.

e. Patient Exhalation Balloon pressure is relieved by (d) and patient pressure falls to atmosphere.

If the THIRD positive pressure breath is normal (does not exceed limit), the audible alarm will discontinue and the visual indicator will remain latched until manually reset with the VISUAL RESET button.

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OPERATION ABOVE 79 cmH_2O

On the first positive pressure breath which exceeds 80 cmH_2O, the following occurs:

a. Visual indicator, HI PRESS, is illuminated and flashing.

b. Audible alarm latches ON.

c. Piston forward motion is halted, terminating volume delivery.

d. Pressure Limit Solenoid Valve is opened.

e. Patient Exhalation Balloon pressure is relieved by (d) and patient pressure falls to atmosphere.

PROLONGED INSPIRATORY PRESSURE

If a sustained (prolonged) high inspiratory pressure occurs due to an occlusion of the exhalation valve system, the following will occur upon the FIRST POSITIVE PRESSURE breath which exceeds the HIGH PRESS ALARM.

a. Visual indicator HIGH PRESS is illuminated and flashing.

b. Pistons forward motion is halted, terminating volume delivery.

c. Pressure Limit Solenoid Valve is opened.

d. Audible alarm latches on after 3 seconds, if pressure has not decreased below the LOW PRESS alarm.

e. No further breaths will be given until pressure decays below the LOW PRESS ALARM setting.

f. If occlusion is not relieved, APNEA will illuminate within 20 seconds.

g. If occlusion is not relieved, VENT INOP will illuminate within 61 seconds.

HI PRESS

Flashing light indicates the HIGH PRESS ALARM has been activated.

LOW PRESSURE ALARM

Adjustable from 3 cmH_2O to 70 cmH_2O in increments of 1 cmH_2O.

When the inspiratory pressure fails to transition through the LOW PRESS ALARM setting on a machine delivered breath, the visual indicator will flash.

If the second positive pressure breath transitions through the low pressure setting, the flashing visual indicator will terminate.

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If the inspiratory patient pressure fails to transition through the LOW PRESS ALARM setting on a second successive breath, the audible alarm will sound and the visual indicator will latch on. The visual indicator now must be manually reset with the VISUAL RESET button. The audible alarm will cease on the next positive pressure breath which transitions through the LOW PRESS ALARM.

LO PRESS

LOW PRESS

Flashing light indicates the LOW PRESS ALARM has been activated.

VENT INOP

VENT INOPERATIVE

This is an audible and visual alarm which indicates one of the following conditions:

- **FAIL TO CYCLE** — IS A VENT INOP condition which occurs after the ventilator has attempted its default program. For an explanation of default, see Theory of Operation.
- **HIGH OR LOW INSPIRATORY TIME** — A VENT INOP condition will occur when the unit operates outside the predefined limits of T_I 0.25 sec. to T_I 4.99 sec.
- **TIMING CIRCUIT FAILURE** — If the master clock that controls both microprocessors fails or shifts, the clock attempts to reset itself (one re-try). If the reset is unsuccessful, the VENT INOP alarm is activated.
- **INTERNAL POWER SUPPLY FAILURE** — If any of the regulated voltages within the unit shift beyond the acceptable limits, then the VENT INOP alarm will be activated.
- **INTERNAL BATTERY POWER INSUFFICIENT TO DRIVE VENTILATOR** — Once the internal battery is discharged beyond its ability to drive the pump, the VENT INOP alarm will activate.

The audible and visual alarms cannot be silenced or reset until the specific ventilator inoperative condition is corrected. Turn off the ventilator, provide another means of ventilation and refer the product to an authorized service technician.

APNEA

APNEA

This alarm has a fixed period of 20 seconds. If the breath interval between any mechanical or spontaneous breath exceeds 20 seconds, the audible and visual alarm will activate. The audible alarm automatically cancels at the next breath. The visual indicator must be reset manually.

NOTE

The detection of spontaneous breaths is dependent upon the ASSIST SENS setting.

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LO BATT

LOW INTERNAL BATTERY ALARM

This indicator will flash accompanied by a continuous audible alarm when there is a minimum of 25% or less operating time available on the internal battery (approximately 15 minutes). The flashing indicator cannot be reset with the VISUAL RESET button.

NOTE

Prior to the continuous low battery alarm, an intermittent low battery alarm may activate during mechanical breath delivery.

If the internal battery continues to be used to power the ventilator, the audible alarm may only be silenced for 60 seconds with the ALARM SILENCE button.

If the power source is changed to either the external battery or WALL AC, the audible alarm will silence automatically. The flashing indicator must be manually reset with the VISUAL RESET button.

(See description of battery charge times, Figure 23.)

WARNING

When the internal battery source is being used and the LO BATT indicator is flashing, it indicates the operating time of the ventilator is limited. The patient should not be left unattended and an alternative power source or means of ventilation MUST be provided.

LOW INTERNAL BATTERY (BELOW 25% OPERATING CAPACITY)

POWER SOURCE:	AUDIBLE ALARM	VISUAL INDICATION
INTERNAL BATTERY	CAN BE SILENCED FOR 60 SECONDS	FLASHING LO BATT
CHANGE TO AC WALL	AUTOMATICALLY CANCELLED	FLASHING LO BATT MAY BE RESET
CHANGE TO EXTERNAL BATTERY	AUTOMATICALLY CANCELLED	FLASHING LO BATT MAY BE RESET

COMPLETE POWER FAILURE ALARM

If all of the power sources available fail (wall AC, external battery, internal battery), then the unit's built-in capacitor will activate the audible alarm for a minimum of one (1) minute. Alarm loudness will diminish as the capacitor's power is depleted and there will be *no indicator lights on* (panel will be completely blank).

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PWR CHANGE

POWER SOURCE CHANGED

Indicates that the ventilator has automatically switched power source under the following conditions:

- Wall AC to external battery.
- Wall AC to internal battery.
- External battery to internal battery.

Any of these conditions will cause an audible and visual alarm indication. Both the audible and visual alarm indication may be cancelled with the VISUAL RESET button.

The audible alarm will automatically cancel upon restoration of the original power source. The visual alarm indicator must be reset manually with the VISUAL RESET button.

ALARM SILENCE

Allows 60 second silencing of all the audible alarms except for VENT INOP.

Silenced audible alarms will reactivate automatically in 60 seconds if the alarm condition still exists. You may manually reactivate the audible alarm capability by depressing the ALARM SILENCE button a second time within the 60 second time frame.

WARNING

The patient should never be left unattended when the ALARM SILENCE button is depressed to allow timely detection of alarm conditions.

SILENCED

ALARM SILENCED INDICATOR

Indicates the audible portion of an alarm capability has been silenced for 60 seconds.

VISUAL RESET

The visual indicators (except for SILENCED) continue flashing after an alarm condition has been corrected. Indicators must be manually reset by depressing the VISUAL RESET button. Visual reset is inhibited while an alarm condition exists. VISUAL RESET also silences the audible power changed and LOW BATT alarms.

NOTE

Although an alarm condition may no longer exist, the illuminated indicator will show an alarm condition has occurred.

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UNLOCKED

UNLOCKED INDICATOR

Indicates the panel is unlocked and will automatically clear 15 seconds after the last key stroke or when the unlock button is depressed a second time.

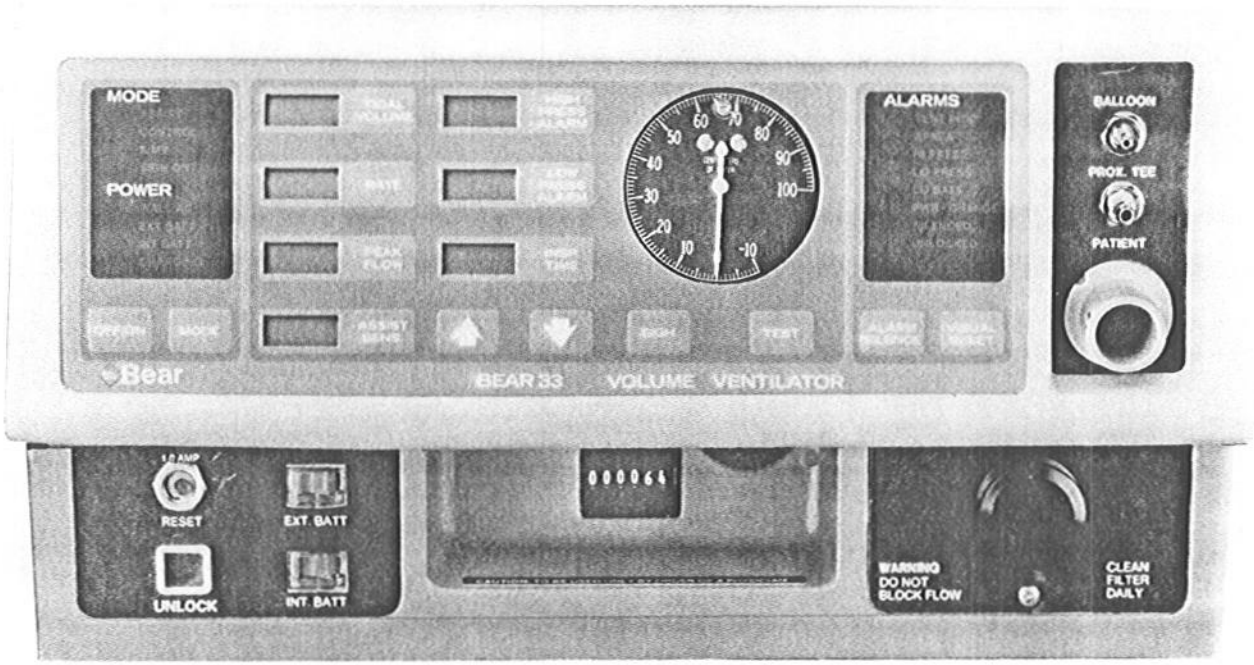

Figure 20

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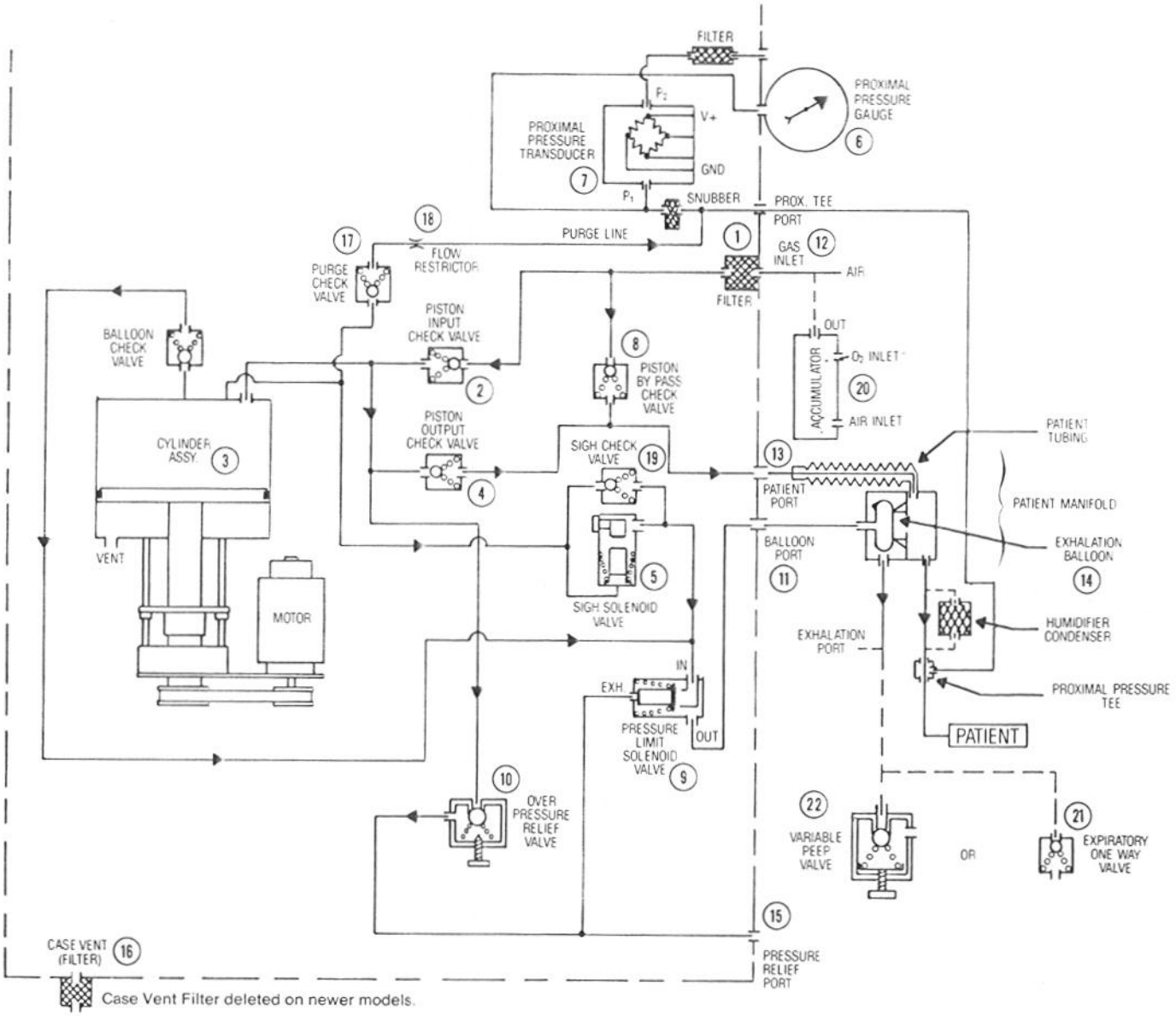
DESCRIPTION OF PNEUMATIC AND ELECTRONIC COMPONENTS

The BEAR® 33 Volume Ventilator utilizes an electronic control system to govern piston gas delivery to the patient. The pneumatic schematic (Figure 21) illustrates all of the major components through which the flow of gas delivered to the patient passes.



NOTE: Schematic shown in "Power On" Condition. Sigh Solenoid is de-energized and pressure limit solenoid is energized.

BEAR® 33 VOLUME VENTILATOR PNEUMATIC SCHEMATIC

Figure 21

(1) GAS INLET FILTER

A 59 micron filter to limit the entry of particulate matter into the ventilator.

(2) CYLINDER INPUT CHECK VALVE

One-way check valve which permits the air to enter the cylinder when the piston retracts. The valve closes on the forward stroke forcing air to exit through the output check valve.

(3) CYLINDER ASSEMBLY

A 2200 cc maximum displacement piston delivers the patient TIDAL VOLUME or SIGH VOLUME. The piston is driven by a variable speed DC motor in a sinusoidal stroke fashion. The motion of the piston is monitored by a digital encoder. The encoder sends information to the microprocessor which controls piston speed and displacement.

An end of stroke sensor is used as a backup to the encoder and is used as the primary reference from which displacement is measured.

TIDAL VOLUME is determined by the distance the piston pulls back from the end of the stroke sensor.

(4) CYLINDER OUTPUT VALVE CHECK

One-way check valve which prevents air, pushed out of the cylinder, from re-entering the cylinder during the return stroke.

(5) SIGH SOLENOID VALVE

An electronically controlled valve (normally open) through which the exhalation balloon drive pressure signal must pass. This valve is only actuated when the sigh volume (1.5 V_T) exceeds 2200 ml.

If the SIGH volume exceeds 2200 ml, the SIGH is delivered in two parts. On the first stroke, the piston delivers a volume of 2000 cc. At the top of the stroke, the SIGH solenoid closes to maintain pressure in the exhalation balloon and the piston quickly retracts to deliver the remainder of the SIGH volume.

(6) PROXIMAL PRESSURE GAUGE

This gauge is connected to the front panel input labelled "PROX. TEE". When a patient circuit is connected, this gauge displays the pressure at the patient interface.

(7) PROXIMAL PRESSURE TRANSDUCER

This electronic transducer senses the pressure in the patient manifold and is used for the following functions:

- HIGH PRESSURE ALARM
- LOW PRESSURE ALARM
- ASSIST SENSITIVITY

(8) CYLINDER BYPASS CHECK VALVE

A one-way check valve which allows the patient to spontaneously breathe gas from the ventilator inlet port. This allows the patient to draw spontaneous breaths, even when the piston is retracting for its next delivery (if a one-way valve is installed). However, the patient must overcome circuit/humidifier resistance, as well as reduce PEEP, to open the bypass check valve. Cracking pressure of the cylinder bypass check valve is -0.2 cmH_2O below atmospheric pressure.

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(9) PRESSURE LIMIT SOLENOID VALVE

This electronically controlled valve is located in the exhalation balloon drive line. When the pressure signal exceeds the HIGH PRESSURE alarm setting, the monitor software causes the valve to open; thereby, venting the exhalation balloon.

(10) OVERPRESSURE RELIEF VALVE

This popoff valve is located between the cylinder and cylinder output check valve. This backup safety valve is designed to open only if pressure in the patient circuit exceeds 85 cmH_2O. It limits pressure to 125 cmH_2O under worst case conditions.

(11) EXHALATION BALLOON OUTPUT

The front panel connector (1/8" barb) which allows attachment of the exhalation balloon drive line.

(12) PROX. TEE INPUT

The front panel fitting (3/16" barb) which allows attachment of the proximal airway pressure sensing line.

(13) PATIENT CIRCUIT OUTPUT

This is the front panel fitting (3/4" barb) for the patient circuit (labeled "PATIENT").

(14) PATIENT MANIFOLD/ EXHALATION BALLOON

The connections on the patient manifold are:

- Gas delivery input from the ventilator
- Gas delivery output to the patient
- Exhalation balloon connection from the ventilator and
- Exhalation port

The exhalation balloon is located in front of the exhalation port and is normally open (with no pressure applied to the balloon). Pressure applied to the balloon input port on the manifold inflates the balloon and occludes the exhalation port. This causes the gas from the ventilator to be directed to the patient port.

(15) PRESSURE RELIEF PORT

This port connects to the output ports of the OVERPRESSURE RELIEF VALVE and the PRESSURE LIMIT VALVE. The output of the two pressure valves may contain high concentrations of O_2 which cannot be vented to the interior of the cabinet. The port is located in the handle well.

(16) VENT FILTER (Does not apply to newer models.)

The 59 micron CASE VENT FILTER insures that the air pumped in and out of the rear of the cylinder mechanism is free of particulate matter.

WARNING

Do not block the case vent filter. The motor may overheat causing the ventilator to malfunction.

CAUTION

DO NOT operate the ventilator without the CASE VENT FILTER in place. Particulate matter that enters the ventilator could cause damage to the finish of the piston cylinder wall.

(17) PURGE CHECK VALVE

Ensures a unidirectional flow of gas through the proximal pressure line from the cylinder to the proximal pressure tee.

(18) FLOW RESTRICTOR

Limits the amount of purge flow received by the proximal pressure line so that the pressure gauge and pressure transducer are not affected by this flow.

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(19) SIGH CHECK VALVE

Ensures adequate balloon pressure on the second piston stroke of a SIGH volume (when a second stroke is needed).

(20) O_2 ACCUMULATOR

A mixing chamber which provides a reservoir of mixed gas, from which the cylinder may draw for delivery of increased FIO_2 through the BEAR® 33 Volume Ventilator to the patient.

WARNING

The O_2 accumulator is NOT a calibrated device and requires the use of an O_2 analyzer in the inspiratory leg of the patient circuit at or near the patient airway. Spontaneous breathing may unfavorably alter the desired FIO_2.

ACCUMULATOR OUTLET

Tubing connects this outlet with the patient air inlet filter port.

INLET FITTING

This inlet fitting is located adjacent to the reservoir output port and accepts a $\frac{5}{32}$" I.D. tube from any flow controlled O_2 source.

ACCUMULATOR AIR INLET

A filtered inlet which allows entry of room air for mixing with the O_2 supply. This inlet is located at the opposite end of the reservoir from the O_2 inlet and the RESERVOIR OUTLET.

(21) EXPIRATORY ONE-WAY VALVE

This valve mounts on the exhalation port of the patient manifold and performs two functions:

- When increased FIO_2 is being used, this valve eliminates patient inhalation through the exhalation port from atmosphere while the balloon is deflated during piston retraction.
- When ASSIST SENSITIVITY is being used, the addition of a one-way valve on the exhalation port may enhance the machine's sensitivity to patient inspiratory efforts, since inhalation of atmospheric gas is prevented.

(22) PEEP VALVE

This optional valve mounts on the exhalation part of the patient manifold. It creates (0-20 cmH_2O) Positive End Expiratory Pressure.

WARNING

Use of PEEP may lead to increased work of breathing in some patients, resulting in rebreathing and CO_2 retention. Evaluate the patient's ability to perform the work of breathing when PEEP is used. The PEEP Valve generates an end expiratory pressure only, and does not maintain CPAP (constant positive airway pressure) during a spontaneous breath.

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NORMAL TIDAL VOLUME DELIVERY

At the end of a delivered breath, the piston is located at the cylinder head. As the piston begins to draw back, the small volume of gas contained in the exhalation balloon is pulled into the cylinder. This opens the exhalation port and allows the patient to exhale. As the piston continues to pull back, the CYLINDER INPUT CHECK VALVE opens and allows the piston to pull air through the GAS INLET FILTER. The piston will retract to a position determined by the TIDAL VOLUME input shown on the front panel digital display.

When the microprocessor commands delivery of the next positive-pressure breath (RATE control or ASSIST SENSITIVITY circuit), the piston drives forward to deliver the TIDAL VOLUME. This delivery of gas to the patient is a sinusoidal waveform and the maximum speed of the piston is determined by the PEAK FLOW setting.

As the piston moves forward, pressure begins to rise and immediately inflates the exhalation balloon. The CYLINDER OUTPUT CHECK VALVE then opens and allows delivery of the TIDAL VOLUME to the patient circuit and the patient (See Figure 21). Tidal Volume Accuracy is ±5% or 20 ml, whichever is greater when zero PEEP is used.

TIDAL VOLUME DELIVERY
With PEEP Levels of 1-20 cmH_2O

Tidal Volume is delivered in the same manner as above. However, the presence of positive end expiratory pressure in the patient circuit causes the exhalation balloon to completely deflate increasing the distance between the balloon and the manifold seat. This can result in some Tidal Volume "blowing by" the balloon during the initial portion of the piston's forward movement; resulting in some Tidal Volume loss.

Blow by is compensated for in the Bear® 33 by preferentially biasing flow (during early piston movement) to the exhalation balloon. Generally blow by will increase as Peak Flow and PEEP level increase. However, Tidal Volume will be accurate to within ±10% of the Tidal Volume setting when PEEP is used.

SIGH VOLUME DELIVERY

Sigh is activated by the SIGH button and indicated by the SIGH ON indicator. Sigh is 1.5 times the TIDAL VOLUME display. For tidal volumes up to 1460 cc, the SIGH volume function operates exactly as described above. Since 1460 x 1.5 = 2190 cc, this is within the capabilities of a single stroke of the piston.

For tidal volumes from 1470 cc to 2200 cc, the corresponding SIGH volumes are 2205 cc to 3300 cc and these are beyond the capability of a single stroke of the piston.

To achieve a SIGH volume beyond the capability of a single piston stroke, the ventilator will deliver two piston strokes, the sum of which is the desired SIGH volume. To accomplish this two-stroke delivery of SIGH volume, a first stroke of the piston delivers 2000 cc. The piston will then quickly pull back and with a second stroke, deliver the remainder of the appropriate SIGH volume.

EXAMPLE	
TIDAL VOLUME	= 1500 cc
CALCULATED SIGH (1.5 x 1500 cc)	= 2250 cc

Therefore:

FIRST PISTON STROKE	= 2000 cc
SECOND PISTON STROKE	= 250 cc
TOTAL SIGH DELIVERED	= 2250 cc

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To accomplish this double stroke delivery of SIGH volume, the SIGH solenoid valve is closed during the piston pull back and the second stroke. The closure of this valve keeps a positive pressure in the exhalation balloon during the pull back, maintaining patient pressure. The second piston stroke delivers gas to the exhalation balloon through the SIGH CHECK VALVE, thus keeping the exhalation valve closed during the second stroke. At the end of the second stroke on a SIGH volume, the SIGH SOLENOID is opened and the normal TIDAL VOLUME delivery is resumed.

The SIGH expiratory time is automatically adjusted to 1.5 x the normal rate determined expiratory time. This allows adequate exhalation of the SIGH breath. The rate window will be shifted as a result.

SPONTANEOUS BREATHING

With the standard BEAR® 33 Volume Ventilator patient manifold (no one-way exhalation valve), the patient has two sources of gas available for spontaneous inhalation. The patient may inhale past the deflated exhalation balloon from atmosphere or through the cylinder bypass check valve in the ventilator. Inhalation will pull from one or both sources, depending on the effort.

If an expiratory one-way valve or PEEP valve is added to the exhalation port of the patient manifold, then the patient inhalation will come solely from the ventilator. When the patient draws solely from the ventilator, the majority of this inhalation will come through the PISTON bypass check valve (cracks at –0.2 cmH_2O). Some gas may be pulled through the cylinder valves. The primary reason for the piston bypass check valve is to allow the patient to inhale spontaneously during the time period that the piston is pulling back in preparation for the next positive pressure breath.

SPONTANEOUS BREATHING WITH PEEP

The Bear® 33 does not incorporate any Pneumatic Demand Valve, leak compensation or PEEP make-up features. Thus, when PEEP is added to the patient circuit, the patient must be capable of reducing the baseline pressure to the cracking pressure of the piston bypass check valve in order to spontaneously breathe. [The piston bypass check valve cracks at –0.2 cmH_2O.] PEEP may lead to increased work of breathing, and may be beyond the capabilities of some patients. Thus, it is important to evaluate the need for PEEP in light of the patient's ability to perform the work of breathing.

WARNING

Use of PEEP may lead to increased work of breathing in some patients, resulting in rebreathing and CO_2 retention. Evaluate the patient's ability to perform the work of breathing when PEEP is used. The PEEP Valve generates an end expiratory pressure only, and does not maintain CPAP (constant positive airway pressure) during a spontaneous breath.

HIGH PRESSURE ALARMS AND LIMIT

The primary system which limits high pressure conditions is the front panel HIGH PRESSURE ALARM, including the proximal pressure transducer and the pressure limit solenoid. Any time the pressure transducer senses a pressure higher than the High Pressure alarm setting, the monitor software will activate the PRESSURE LIMIT SOLENOID VALVE which vents exhalation balloon pressure and thus, the patient circuit pressure. The monitor software will simultaneously stop the forward motion of the piston until the pressure falls below the Low Pressure alarm setting. The piston will then move to the home position with the exhalation balloon remaining open. After the

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activation of the HIGH PRESS indicator, the pressure is monitored. If the pressure does not decrease below the LOW PRESS ALARM setting within three (3) seconds, the audible alarm will latch on. When the proximal pressure has reduced to the LOW PRESSURE alarm setting and the piston has reached home, the pressure limit solenoid will close and allow the ventilator to deliver any succeeding positive pressure breaths.

NOTE

If the proximal pressure exceeds 80 cmH_2O, the HIGH PRESSURE visual and audible alarm will latch on upon the first occurrence. This differs from the normal high pressure alarms (below 80 cmH_2O) violation which requires two occurrences to latch on to the audible portion of the alarm.

OVERPRESSURE RELIEF VALVE

The OVERPRESSSURE RELIEF VALVE is a backup to the HIGH PRESSURE ALARM/LIMIT system. Should that system fail and allow inspiratory pressures to exceed 85 cmH_2O, this valve will open. Peak pressure attained in the patient circuit will be limited to a maximum of 125 cmH_2O (at 120 LPM flow rate).

PRESSURE RELIEF PORT

The outputs of the PRESSURE LIMIT SOLENOID VALVE are connected to the PRESSURE RELIEF PORT which is located in the ventilator handle well. This porting insures that any ventilator gas with an FIO_2 above 21% is dumped outside of the ventilator case.

CAUTION

Do not block the PRESSURE RELIEF PORT.

DETERMINING OXYGEN FLOW RATES

The oxygen accumulator is a labyrinth device which allows air and oxygen to mix before entering the ventilator. The O_2 flow into the accumulator is constant and continues to enrich accumulator gas during both patient inspiration and exhalation.

The following chart will give you an *approximate starting point* for O_2 flow into the accumulator. Once the starting point is determined, use an O_2 analyzer to accurately set the desired FIO_2. The chart assumes the patient does not breathe simultaneously. Spontaneous breathing may unfavorably alter the desired FIO_2.

WARNING

The O_2 accumulator is NOT a calibrated device and requires the use of an O_2 analyzer in the inspiratory leg of the patient circuit at or near the patient airway. Spontaneous breathing may unfavorably alter the desired FIO_2.

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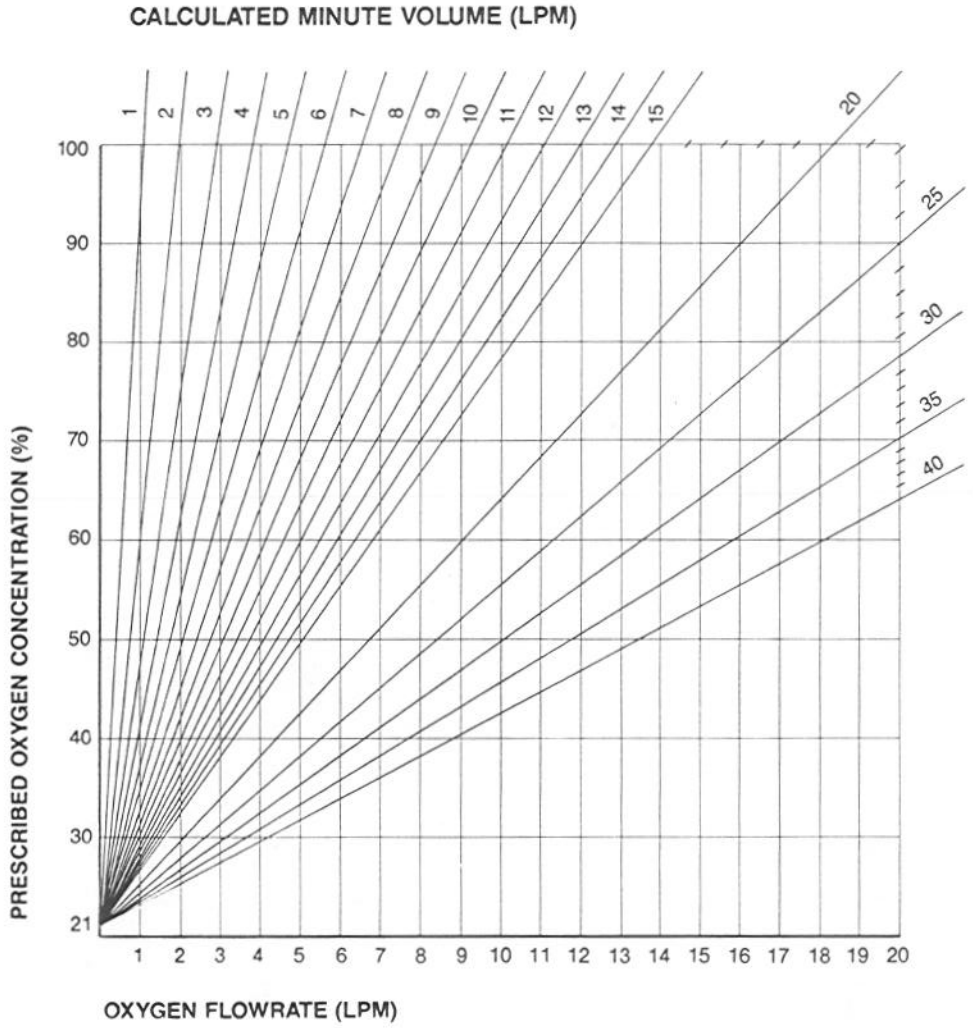
BEAR® 33 VOLUME VENTILATOR OXYGEN ACCUMULATOR CHART



NOTE

The oxygen accumulator is not a calibrated device. The oxygen concentration depends on the RATE, TIDAL VOLUME, OXYGEN INPUT and LEVEL OF SPONTANEOUS BREATHING.

Always follow your doctor's recommendations for the oxygen concentration to use.

This chart is only a guide to the initial oxygen input flowrate; fine adjustment will be required. Allow several minutes for the concentration to stabilize before analyzing or adjusting.

HOW TO USE THE OXYGEN ACCUMULATOR CHART

BEFORE YOU START: Calculate the minute volume by multiplying the following formula:

TIDAL VOLUME × RATE × 0.001= MINUTE VOLUME

Examples: Tidal Volume		Rate			Minute Volume
500	×	16	× 0.001	=	8 LPM
900	×	8	× 0.001	=	7.2 LPM

STEP 1. Find your nearest calculated minute volume line (to the nearest whole number) at the top of the chart. With a ruler and pen trace over your diagonal line minute volume line.

STEP 2. Find the prescribed oxygen concentration ordered by the doctor on the left of the graph. With a ruler and pen, draw a line across the chart at the level of your oxygen concentration.

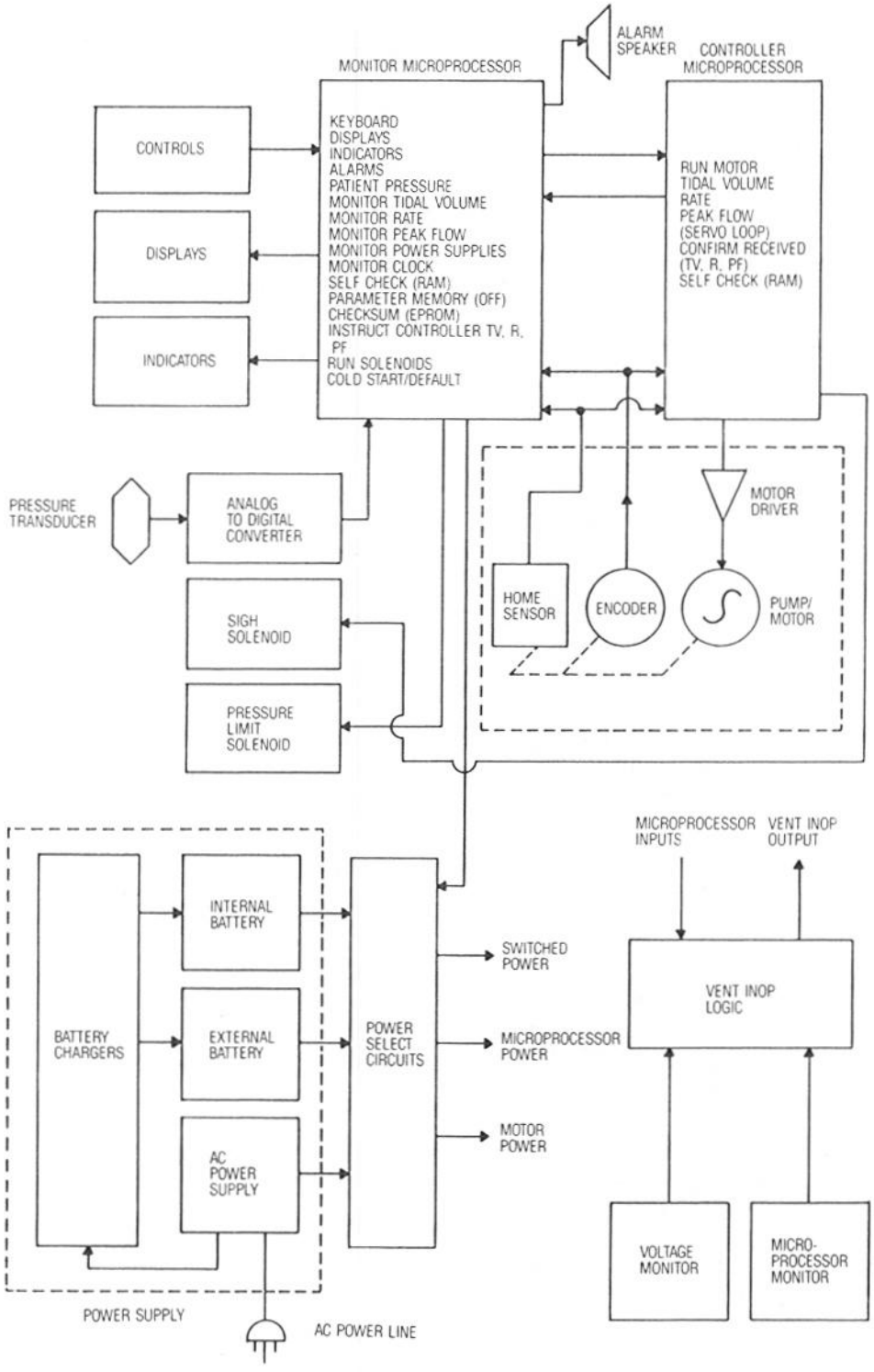
STEP 3. At the point where the minute volume line and oxygen line that you have drawn intersect, draw a vertical line down to the bottom of the chart.

STEP 4. Follow the vertical line down to the bottom of the graph and read the number to the closest 1/2 LPM.

STEP 5. Set the number found in step 4 on the oxygen flowmeter. Be sure to read the center of the flowmeter ball.

STEP 6. Measure the oxygen concentration with an oxygen analyzer, obtained from your rental/homecare dealer.

STEP 7. After two minutes, adjust the flowmeter slightly to achieve the ordered oxygen concentration.



ELECTRONIC BLOCK DIAGRAM

Figure 22

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POWER SOURCE

There are three potential sources of power for operation of the ventilator. These sources are automatically selected by the ventilator on a priority system. The sources and their priorities are as follows:

POWER SOURCE	PRIORITY
AC WALL POWER	1
DC EXTERNAL BATTERY	2
DC INTERNAL BATTERY	3

AC wall power is PRIORITY 1 because of its reliability and ability to recharge the other power sources.

DC external power (12V battery) is PRIORITY 2 because the length of time it can operate the unit is significantly longer than the internal battery.

DC internal battery (12V) is the *LAST* power source priority because it may only operate the ventilator for one hour under all potential operating conditions.

WARNING

The internal battery is a backup source of power for use during emergencies and transition between power source changes of PRIORITIES 1 and 2. The patient should not be left unattended at any time during use of the internal battery source.

When the unit is operating on an internal battery, another power source should be sought immediately.

The ventilator automatically selects its power source based on the above PRIORITIES, 1 then 2, then 3. Any time the ventilator switches from a higher to a lower priority power source, there is an audible alarm and visual POWER CHANGE indicator to show this has occurred. If the ventilator is on a PRIORITY 2 or 3 source and a higher priority source becomes available (i.e., restoration of AC wall power or addition of a charged external battery), the ventilator will automatically switch to the highest priority of choice.

CAUTION

When the ventilator is not being used, leave the unit plugged into the wall to maintain the charge on the internal battery.

DESCRIPTION OF BATTERY CHARGE TIMES

INTERNAL BATTERY

The internal battery operates for approximately one hour depending on the patient ventilation parameters of minute volume, peak airway pressure and ambient temperature. For instance, under maximum minute ventilation and maximum peak airway pressure at 32°F, battery life is reduced by not more than 50% of the one hour rating.

The ability to recharge the internal battery to its full operating capacity will vary depending on the rate of the preceding discharge, time since discharge and to some extent, battery temperature. To recharge, plug the ventilator into an active AC wall outlet.

The following graph indicates the recharge time for the capacity desired for the internal battery. See the maintenance section for further information regarding batteries.

NOTE

Check the battery charge level with the AC power disconnected, and the unit running, since the battery meter indicates the charging process.

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CAPACITY RETURNED vs.
CHARGING TIME @72°F

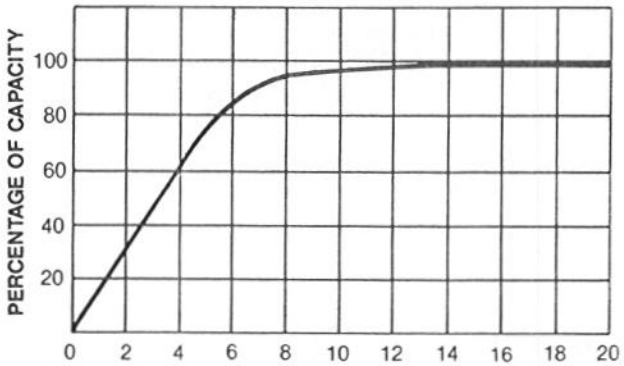

Figure 23

CAUTION

When the ventilator is not being used, turn the power off. However, leave the unit plugged into the wall. Failure to do this may shorten the life of the internal battery.

EXTERNAL BATTERY

The operating time of the external battery depends on the Ampere Rating of the battery. Refer to the manufacturer specifications.

The external battery charger puts out a maximum charge current of 2 amps. Generally, recharge time on an external battery will be one (1) to one and a half (1½) times as long as the discharge time.

Always check the EXT BATT charge status meter on the front of the ventilator for a guide to charging the external battery or when operating from the external battery.

NOTE

Optimum battery operation and maximum battery life will be maintained if the batteries are kept charged to capacity. Always recharge the batteries as soon as possible after use.

POWER ON

Depression of the ON/OFF button activates the ventilator electronics such that the previously entered parameter values are displayed on all LCD functions. Memory of previous parameters will be maintained by the ventilator for three months on a fully charged internal battery.

All ventilator controls, displays, alarms and indicators are functional in all modes with one exception. The ASSIST SENSITIVITY control and display is active only in ASSIST CONTROL and SIMV modes. The ASSIST SENSITIVITY display can be changed in the CONTROL mode to facilitate set-up.

MICROPROCESSOR CONTROL

The operation of the ventilator is controlled by two microprocessors. One controls a variable speed DC motor to deliver the required tidal volume, flow waveform, inspiratory time and rate (the controller). The second microprocessor (the monitor) communicates with the first microprocessor and monitors its operation.

The monitor microprocessor also operates the front panel keys and displays, processes all alarm conditions, switches power sources when needed and monitors patient pressure via the pressure transducer. The patient pressure information is used to determine high and low pressure alarm conditions and to detect a patient effort when in the ASSIST control and SIMV modes.

Both microprocessors, along with additional electronics, monitor voltages and the microprocessor function.

CALCULATION OF INSPIRATORY TIME

INSPIRATORY TIME (T_I) is dependent on TIDAL VOLUME (V_T) and PEAK FLOW ($\dot{V}$peak) set by the operator. The pistons stroke creates a sine wave flow pattern. Thus, the flow rate rises to and falls from the peak during the inspiratory cycle.

BEAR® 33 VOLUME VENTILATOR PEAK FLOW (LPM)	EQUIVALENT SQUARE WAVE FLOW (LPM)
20	12.7
40	25.5
60	38.2
80	50
100	64
120	76

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Note: BEAR® 33 Volume Ventilator PEAK FLOW SETTING x 0.637 = Equivalent Square Wave.

The microprocessor calculates T_I as follows:

$$\dot{V}peak = \left(\frac{60}{0.637}\right)\left(\frac{V_T}{T_I}\right) \quad (1)$$

Operators may verify T_I with the rewritten formula:

$$T_I = (60 \bullet V_T) \div (0.637 \bullet \dot{V}peak) \quad (2)$$

Where $\dot{V}$peak is peak flow in LPM,
V_T is TIDAL VOLUME in liters,
T_I is INSPIRATORY TIME in seconds, carried to two decimal places.
T_I value is not rounded off.
e.g., T_I (calculated) = 1.719, displayed 1.71.

COLD START

If all sources of power are lost or removed (AC, External DC, Internal DC), the COLD START parameters will automatically be shown on the LCD displays when power is reapplied to the ventilator. The cold start parameters are:

RATE	— 16 BPM
TIDAL VOLUME	— 500 cc
PEAK FLOW	— 35 LPM
HIGH PRESS ALARM	— 40 cmH_2O
LOW PRESS ALARM	— 10 cmH_2O
MODE	— ASSIST CONTROL
ASSIST SENSITIVITY	— -1 cmH_2O

DEFAULT PROGRAM

The BEAR® 33 Volume Ventilator microprocessor is protected in a number of ways from power surges and electromagnetic interference.

The BEAR® 33 Volume Ventilator is equipped with a default program which activates if the users input settings are lost from memory either in whole or part. Therefore, the default program protects against a total cessation of ventilation if the random access memory were lost due to an electromagnetic interference.

The following conditions will activate the default program:

1. TIDAL VOLUME — A shift of ±30% of setting.
2. RATE — A shift of ±30% of setting in control mode, or -30% of setting in ASSIST or SIMV modes.
3. PEAK FLOW — A shift of ±30% of setting.
4. Scrambled RAM — Random access memory lost.
5. Inspiratory Time — Outside the 0.25 sec to 4.99 sec range.

If any of these conditions are detected, the microprocessor will attempt to re-establish the set parameters. If it fails to do this, on the next attempted breath, the ventilator will automatically switch to the default parameters. These are:

RATE	— 16 BPM
VOLUME	— 500 cc
FLOW	— 35 LPM
HI PRESS	— 40 cmH_2O
LO PRESS	— 10 cmH_2O
MODE	— ASSIST CONTROL
SENS	— -1 cmH_2O

These parameters are not programmable. They are a compromise group of settings for both pediatric and adult patients. They ensure some ventilation will take place in the face of a serious shift in microprocessor parameter control or total loss of RAM.

If the default program activates, the following will occur:

1. Audible alarm will sound.
2. LCD's will flash the default parameters.
3. All alarm indicators are still operational.

WARNING

Default parameters are not the original parameters set and may not be satisfactory for your patient's condition. Insure adequate ventilation of your patient and take corrective action.

CORRECTIVE ACTION

1. Insure adequate ventilation of your patient.
2. Press panel unlock.
3. Turn power OFF, then ON.

NOTE

Cold start parameters will appear in LCD's, and flashing should stop.

4. Reset patient prescribed settings as outlined in the set-up protocol.

WARNING

Should the ventilator re-enter a default condition, provide an alternative source of ventilation and contact a qualified Service Technician.

The BEAR® 33 Volume Ventilator is equipped with Error Codes to assist the clinician and service technician in trouble shooting. Error Codes are set by the monitor program upon detection of a Vent Inop condition. An Error Code will be displayed in the Tidal Volume LCD display as an "E" followed by a number 01 to 13 i.e., (E02). The Error codes and descriptions are as follows:

BEAR® 33 Volume Ventilator Error	Error Code Description
E01	Random Access Memory Verification Error
E02	Serial Input/Output Time Out
E03	Read Only Memory Check Sum Error
E04	7.15v Out of Tolerance
E05	5.00v Out of Tolerance
E06	Received Data Start Bit Error
E07	Received Data Error
E08	Home Signal Timeout
E09	Monitor Overflow
E10	Monitored Rate Error
E11	Monitored Ti Error
E12	Monitored Vt Error
E13	Monitored Sigh Error

If Vent Inop Condition should occur, note the Error Code in the tidal volume display. This will assist the service department in determining the cause and likely repair required. For further information, refer to the BEAR® 33 Service Manual or call Bear Medical's Service Department.

WARNING

If the VENT INOP alarm activates, it indicates an internal malfunction. Under such circumstances, the ventilator must be removed from the patient and a back-up system immediately provided, and referred to a qualified service technician. The VENT INOP alarm can only be silenced by turning the ventilator OFF or correcting the VENT INOP condition.

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SIMV THEORY OF OPERATION

The synchronized mandatory breath rate is controlled by the RATE control. Respiratory rates as low as two breaths every minute are available. When the mandatory breath is due to be delivered, the assist trigger mechanism is activated to sense the patient's inspiratory effort. Upon sensing the patient's next inspiratory effort, the ventilator delivers the preset TIDAL VOLUME at the preset flow rate selected on the control panel (Synchronous IMV). As soon as the mandatory breath volume has been delivered, the assist mechanism is deactivated. The patient then continues spontaneous breathing until the next mandatory breath is due.

If the patient has a period of apnea, a positive-pressure breath will be delivered at the next mandatory breath time sequence (Asynchronous IMV). The ventilator will continue to deliver controlled breaths according to the respiratory rate setting on the RATE control until the next inspiratory effort from the patient is seen. This causes the time sequence to be reset.

A breath interval greater than the APNEA PERIOD alarm setting (20 sec) or a rate which would allow periods between CONTROLLED breaths to be longer than the alarm setting, would initiate the audible and visual apnea alarm. Figure 24 shows a typical example of SIMV in operation with the patient breathing spontaneously. In this example, the SIMV rate on the Ventilator is set to deliver 6 BPM. Therefore, the patient would receive a machine breath (mandatory breath) approximately every 10 seconds (60 seconds ÷ 6 BPM). This 10-second period is referred to as the fundamental time period.

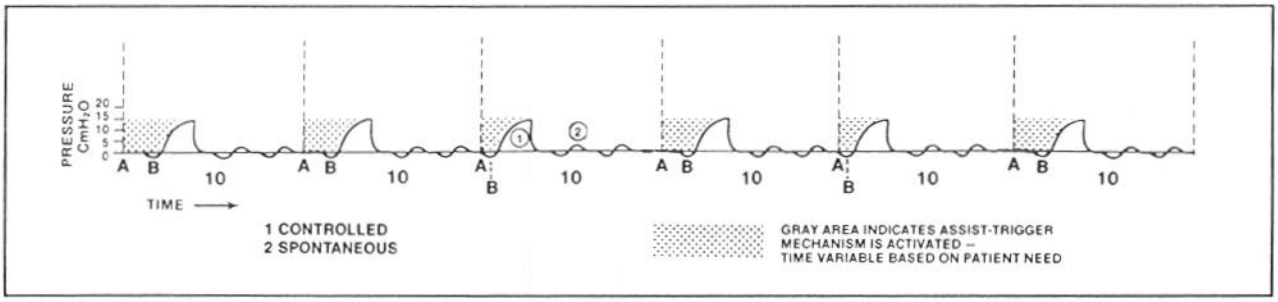

FIGURE 24 BEAR® 33 VENTILATOR SIMV OPERATION — NORMAL

At the onset of the first fundamental time period (A), a 10-second timing window begins and the ventilator becomes an assist-controller. This means that the next patient effort triggers a ventilator synchronized breath (Point B). At initiation of the assisted breath, the assist mechanism deactivates for the remainder of that fundamental time period. Subsequent breaths in that time period are spontaneous and the patient breathes through the Piston Bypass Check Valve. The assist mechanism reactivates at the onset of the next fundamental time period.

In the first fundamental time period, the patient triggers an assisted breath and then breathes spontaneously through the bypass valve. Figure 25 depicts the condition in which the patient goes apneic.

In the second fundamental time period, the patient receives a synchronized mandatory breath, exhales and then becomes apneic (Point C). Note that at Point C the assist mechanism is deactivated for the remainder of that fundamental time period since the patient has received a ventilator synchronized breath.

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At the start of the third fundamental time period (Point D), the assist mechanism reactivates, waiting for the patient to initiate a breath. At the end of this 10-second interval, a mandatory breath is delivered even when no inspiratory effort is sensed (Point E).

During the fourth fundamental time period, the assist mechanism remains activated since the mandatory breath is not initiated by the patient. At Point F, the patient resumes spontaneous breathing. The assist mechanism senses an inspiratory effort and delivers a synchronized breath. Following exhalation of this breath, the patient continues to breathe spontaneously (Point G). Note that although the patient went apneic, only the time period between mandatory breaths varied. The overall mandatory breaths per minute and mandatory minute volume remained the same.

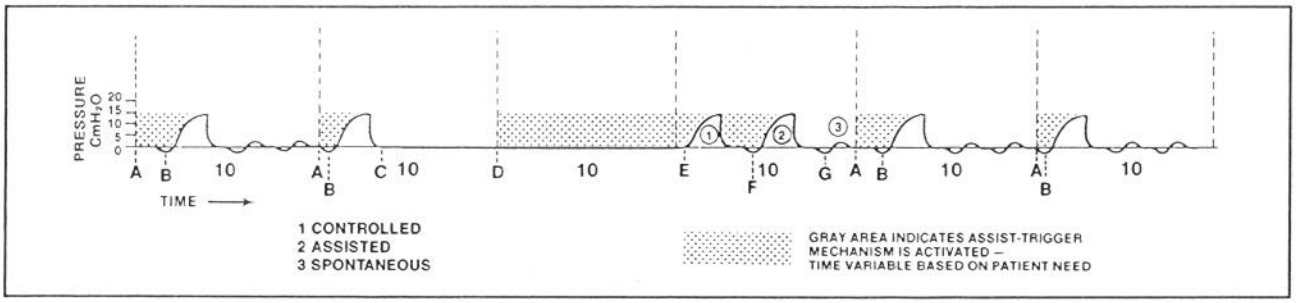

FIGURE 25 BEAR® 33 VENTILATOR SIMV OPERATION PATIENT APNEIC

WARNING

The ASSIST SENSITIVITY control must be properly adjusted in the SIMV mode to insure accurate monitoring of spontaneous breaths. It is necessary to properly set the ASSIST SENSITIVITY control in the SIMV mode to synchronize patient effort with ASSISTED and CONTROLLED breaths. Improper adjustment could lead to stacking CONTROLLED breaths on top of the patient's spontaneous breaths (if the sensitivity control is set higher than actual patient effort).

WARNING

ASSIST SENSITIVITY must be set below patient baseline pressure in ASSIST CONTROL and SIMV modes to prevent autocycling.

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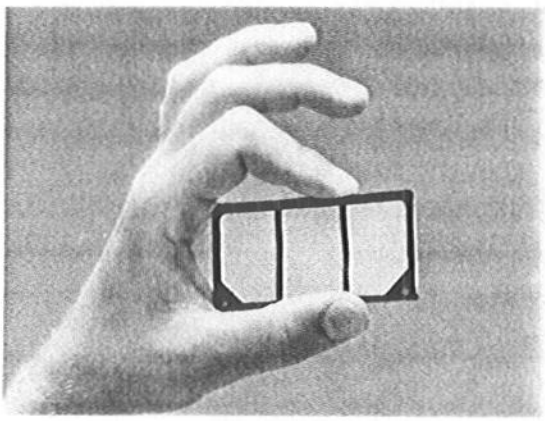
PREPARATION OF THE VENTILATOR

1. Check the GAS INLET filter on the front panel and the CASE VENT filter (if present) for dirt. Clean if necessary (see Cleaning Instructions).



CAUTION

DO NOT operate the ventilator without the GAS INLET FILTER. Particulate matter that enters the ventilator could cause damage to the finish of the cylinder wall. Do not block or occlude the gas inlet.

2. Plug the ventilator into a *grounded* outlet. The CHARGING indicator will illuminate on the front panel.

NOTE

This ventilator is equipped with a 3-prong plug. If the electrical receptacle box does not have a 3-prong capacity, a grounding adapter *must* be used. The adapter's grounding leadwire must be firmly attached to a grounded receptacle box. If there is any doubt as to whether or not the receptacle box is grounded, it should be checked by an electrician.

3. Depress the TEST button and observe that all the indicators and all segments of the LCD displays illuminate, showing they are operational. Observe the audible alarm has sounded.

WARNING

If the CHARGING indicator does not illuminate when the unit is plugged into an active wall source, or the indicators or LCD display segments do not illuminate during TEST or the audible alarm does not sound during TEST, refer the BEAR® 33 Volume Ventilator to a qualified service technician. DO NOT OPERATE THE VENTILATOR WITHOUT ALL DISPLAYS, INDICATORS AND AUDIBLE ALARMS FUNCTIONAL.

TESTING THE CIRCUIT FOR LEAKS

1. Connect a rubber test lung to the free end of the patient tracheostomy flextube connector.
2. Depress the OFF/ON button.
3. Depress the UNLOCK button.
4. Set the RATE to 10 BPM.
5. Set the TIDAL VOLUME to 500 ml.
6. Set the PEAK FLOW to 20 LPM.
7. Set the HIGH PRESS ALARM to 80 cmH_2O.
8. Remove the test lung.
9. Occlude the tracheostomy flextube adapter with your thumb.
10. Observe that the pressure reaches 80 cmH_2O (watch the pressure manometer) and the audible alarm sounds.
11. Verify the HI PRESS indicator illuminates.
12. If the audible alarm does not sound and the HI PRESS indicator does not illuminate, check the circuit for leaks.
13. If no leaks are found and the audible alarm does not sound or the visual indicator does not illuminate, turn the ventilator off and refer the unit to an authorized service technician.
14. If the audible alarm does sound and the visual indicator illuminates, reconnect the test lung and reset the visual indicator with the VISUAL RESET button.

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TESTING THE HIGH PRESSURE ALARM

1. Connect a rubber test lung to the free end of the patient tracheostomy flextube connector.
2. Depress the UNLOCK button.
3. Set the TIDAL VOLUME control to the desired setting.
4. Set the HIGH PRESS ALARM to the desired setting.
5. Remove the test lung.
6. Occlude the tracheostomy flextube adapter with your thumb.
7. Observe that the ventilator relieves the pressure and the piston repositions to deliver the next breath.
8. Verify the audible alarm sounds on the second successive breath and the HI PRESS indicator illuminates.
9. If the audible alarm does not sound and the HI PRESS indicator does not illuminate, turn the ventilator off and refer the unit to an authorized service technician.
10. If the audible alarm does sound and the visual indicator illuminates, reconnect the test lung and reset the visual indicator with the VISUAL RESET button.

NOTE

The BEAR® 33 Volume Ventilator front panel is always in the locked position. To set controls, the panel must be unlocked with the UNLOCKED button. The panel will be unlocked for 15 seconds from the last key stroke.

TESTING THE LOW PRESSURE ALARM

1. Connect a rubber test lung to the free end of the patient tracheostomy flextube connector.
2. Depress the UNLOCK button.
3. Set the TIDAL VOLUME control to the desired setting.
4. Set the LOW PRESS ALARM control to the desired setting.
5. Remove the test lung.
6. Verify the audible alarm sounds and the LO PRESS indicator illuminates after two (2) successive breaths.
7. If the audible alarm does not sound or the visual indicator does not illuminate, turn the ventilator off and refer the unit to an authorized service technician.
8. If the audible alarm does sound and the visual indicator illuminates, reconnect the test lung, and reset the visual indicator with the VISUAL RESET button.

TESTING THE APNEA ALARM

1. Connect a rubber test lung to the free end of the patient trachestomy flextube connector.
2. Depress the UNLOCK button.
3. Set the RATE control to 2.0 BPM.
4. Set the MODE to ASSIST CONTROL.
5. Set the LOW PRESS ALARM setting above 60 cmH_2O.
6. Remove the test lung.
7. Verify the audible alarm sounds after 20 seconds and the APNEA indicator illuminates.
8. If the audible alarm does not sound or the visual indicator does not illuminate, turn the ventilator off and refer the unit to an authorized service technician.
9. If the audible alarm does sound and the visual indicator illuminates, reconnect the test lung and reset the visual indicator with the VISUAL RESET button.

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TESTING THE POWER CHANGE ALARM

1. With the ventilator turned on, unplug the AC power cord.
2. Verify the INT BATT indicator illuminates (or EXT BATT, if connected).
3. Verify the POWER CHANGE indicator illuminates and an audible alarm sounds.
4. If the audible alarm does not sound or the visual indicator does not illuminate, turn the ventilator off and refer the unit to an authorized service technician.
5. If the audible alarm does sound and the visual indicator illuminates, cancel the audible alarm with the ALARM SILENCE button and the POWER CHANGE indicator with the VISUAL RESET button.

WARNING

The visual indicators, digital display segments, HIGH PRESSURE ALARM, LOW PRESSURE ALARM, APNEA ALARM and POWER CHANGE ALARM should be verified daily.

SETTING THE VENTILATOR

1. Connect a rubber test lung to the free end of the patient tracheostomy flextube connector.
2. Depress the OFF/ON button.

NOTE

The ventilator settings will be those which were last set. You may, at this time, set alarms which should be silenced.

3. Unlock the control panel with the UNLOCK button.
4. Select the desired mode with the MODE button.
5. If SIGH is desired, select sigh with the SIGH button.
6. Set the desired tidal volume using the TIDAL VOLUME button and the appropriate UP or DOWN button.
7. Set the desired rate using the RATE button and the appropriate UP or DOWN button.
8. Set the desired peak flow using the PEAK FLOW button and appropriate UP or DOWN button.
9. If in the ASSIST CONTROL or SIMV mode, set ASSIST SENSITIVITY to the desired level by using the ASSIST SENS button and the appropriate UP or DOWN button.
10. Set the HI PRESS ALARM at the estimated high pressure setting.
11. Set the LOW PRESSURE ALARM at the estimated low pressure setting.
12. If increased FIO_2 is used, adjust the O_2 flowmeter until the desired concentration is observed on the O_2 monitor.
13. Remove the bag and connect the patient.
14. If you are in the ASSIST CONTROL or SIMV mode, observe the ASSIST SENS display. Patient triggering is indicated by a flashing "A" on the left side of this display.

    If the ASSIST SENS is set to its most sensitive position (1 cmH_2O below baseline) and you are not detecting the patient effort, the sensitivity of the system may be increased by the addition of the one-way valve on the exhalation port of the patient manifold.
15. Observe the FIO_2 reading on the O_2 monitor to insure the desired FIO_2 is maintained.

NOTE

In ASSIST CONTROL and SIMV, the patient triggering and spontaneous breathing will alter the minute volume delivered to the patient. An unfavorable FIO_2 may result. Titrate the O_2 flow accordingly.

CLEANING

VENTILATOR EXTERIOR

Before cleaning the exterior of the ventilator, the power cords of the ventilator should be unplugged. The exterior of the ventilator may be wiped clean with an appropriate bactericidal or germicidal agent, alcohol or soap and water. Only alcohol or soap and water should be used to clean the battery and hour meters. Care should be exercised not to allow the liquid agents to penetrate the inside of the ventilator.

CAUTION

Do not gas sterilize or steam autoclave the ventilator. The internal components are not compatible with sterilization techniques.

PATIENT CIRCUIT

The entire patient circuit system should be cleaned per Center for Disease Control (C.D.C.) recommendations. All items of the patient circuit, except for the condenser humidifier or any in-line thermometer should be cleaned with a warm soap and water solution, thoroughly rinsed with warm water and air dried. See Cleaning and Sterilization Table for recommended techniques.

The following parts are included in the patient circuit system:

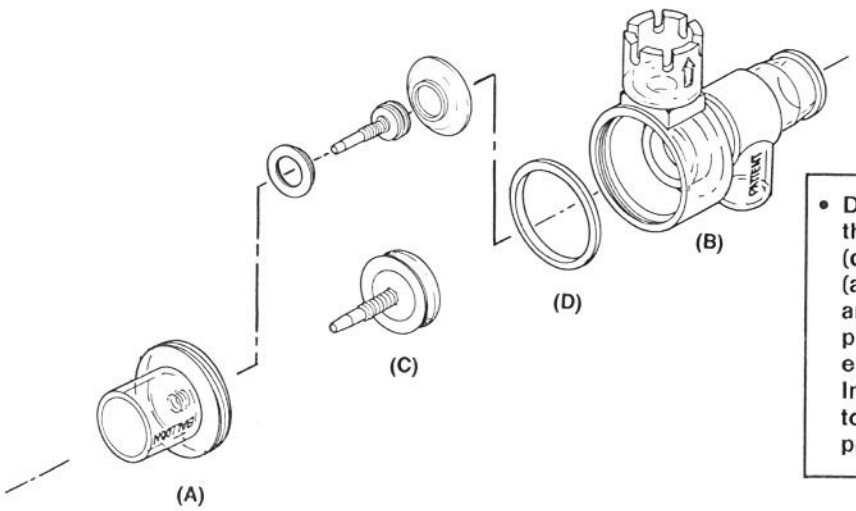
9″ Bacteria Filter Tubing
5″ Patient Tubing
18″ Humidifier Tubing
Exhalation Balloon Tubing (1/8″ I.D. PVC)
Proximal Pressure Tubing (3/16″ I.D. PVC)
Proximal Pressure Tee
4″ Flextube
Coupler
One-way Valve with Coupler (optional)
Tubing Clips

Once cleaned, these parts are prepared to be sterilized.

PATIENT MANIFOLD

The patient manifold should be cleaned at least twice per week or following each patient use.

The manifold is comprised of four (4) pieces and must be disassembled for cleaning and inspection.



WARNINGS

- **During reassembly ensure that the Exhalation Balloon assembly (c) is completely screwed into part (a) so that the two surfaces are flush and tight. If the balloon (c) is not properly seated (to a) excessive exhalation resistance may occur. Inspect the manifold after assembly to ensure that the seal (d) is properly seated and not deformed.**

BEAR® 33 VOLUME VENTILATOR PATIENT MANIFOLD
EXPLODED VIEW
Figure 26

Disassemble the valve as shown in Figure 24 by unscrewing Part A from Part B. To remove the exhalation balloon, unscrew Part C. Remove Part D.

Clean the components (Parts A, B, C and D) with a warm soap and water solution, thoroughly rinse with warm water and air dry.

Inspect the exhalation balloon (Part C) for wear and tear. Replace the valve (50000-03106), if necessary. If the balloon is not disassembled, clean by wiping down the outside of the balloon with soap and water, rinsing and air drying.

Should water get inside the exhalation balloon, disassemble and thoroughly dry before reuse.

WARNING

DO NOT use the exhalation balloon with any moisture inside the balloon. Water may inhibit proper inflation of the balloon resulting in a loss of Tidal Volume.

WARNING

Do not use the Patient Manifold without the Exhalation Valve Seal. The balloon assembly will not seat properly without the Exhalation Valve Seal in place, which may cause greater work to exhale.

WARNING

Do not overtighten the Exhalation Valve Seal assembly. Overtightening may cause seal distortion which could interfere with proper Exhalation Balloon function. Inspect the seal after assembly to ensure proper balloon function.

CAUTION

Do not autoclave or ETO sterilize the Patient Manifold with the Exhalation Valve Seal tightly compressed. Deformation of the seal and loss of function may occur.

MAIN FLOW BACTERIA FILTER

Under no circumstances should this filter ever be cleaned internally. The external surface may be cleaned with alcohol and the filter may be sterilized by steam autoclave (250°F).

CONDENSER HUMIDIFIER

Follow manufacturer's recommended instructions.

O_2 ACCUMULATOR

Clean with soap and water, thoroughly rinse with warm water and air dry (air dry foam filter).

PLUGS AND CABLES

May be wiped down with alcohol after being disconnected.

STERILIZATION

Once the various components have been cleaned and dried, they may be sterilized by an appropriate method.

CAUTION

Do not gas sterilize or steam autoclave the ventilator.

CLEANING AND STERILIZATION TABLE

Item #	Item	Alcohol Wipe External	Soap & Water	Cidex Sonacide	ETO	Steam Autoclave	Maximum Temp. (F)
1	ALL PATIENT TUBING	—	X	X	X	X	250°
2	MAIN FLOW BACTERIA FILTER	X	—	—	—	X	250°
3	PROXIMAL PRESSURE TEE ADAPTER	—	X	X	X	X	300°
4	PATIENT MANIFOLD	—	X	X	X	—	150°
5	PROXIMAL TUBING	—	X	X	X	X	300°
6	EXHALATION VALVE TUBING	—	X	X	X	X	300°
7	ONE-WAY VALVE	—	X	X	X	—	
8	FLEXTUBE	—	X	X	X	X	300°
9	*CONDENSER HUMIDIFIER	X	—	—	—	—	
10	COUPLER	—	X	X	X	X	300°
11	VENTILATOR INLET FILTERS	—	X	X	X	X	300°
12	FRONT PANEL (CASE)	X	X	X	—	—	
13	POWER CORD	X	X	X	—	—	
14	PLUG	X	X	X	—	—	
15	WALLS (CASE)	X	X	X	—	—	
16	BATTERY & HOUR METER	X	X	—	—	—	
17	BATTERY CABLES	X	X	—	—	—	
18	O_2 ACCUMULATOR	—	X	X	X		300°

*Or follow manufacturer's recommendation.

MAINTENANCE

A well-structured maintenance program is essential for continuous, uninterrupted functioning of the ventilator system. Observe the following instructions:

ROUTINE

TUBING AND ADAPTERS — Replace any damaged or leaking tubes or adapters.

MAIN FLOW BACTERIA FILTER — Beyond care during handling and sterilization, maintenance of a bacteria filter is limited to replacement of the filter when it becomes so loaded with particles that if offers too great a resistance to the flow of gas. The bacteria filter should be replaced once per year or more often if the resistance to flow exceeds 4.0 cmH_2O at 120 LPM. It is recommended, in addition to stamping a one-year retirement date on the filter, that a simple test be made to determine resistance to flow.

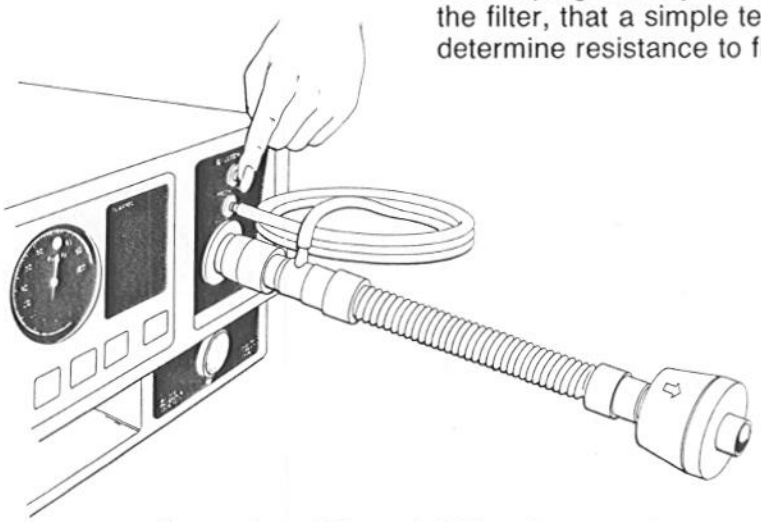


Illustration of Bacterial Filter Test
Figure 27

1. Remove the patient circuit from the ventilator outlet.
2. Connect a universal adapter to the 22 mm output connector labelled "PATIENT" on the front of the ventilator.
3. Attach the proximal pressure tee to the universal adapter.
4. Attach the proximal pressure tee to the front of the ventilator with a piece of 3/16" PVC tubing.
5. Connect the 9" bacterial filter tubing to the free end of the proximal pressure tee.
6. Attach the main flow bacteria filter to the free end of the 9" bacteria filter tubing. Observe the proper flow direction.
7. UNLOCK the panel.
8. Set the PEAK FLOW control to 120 LPM.
9. Set the TIDAL VOLUME control to 1500 cc.
10. Set the RATE control to 10 BPM.
11. With gas flowing through the filter, read the pressure gauge and note the pressure.
12. Remove the filter and circuit components.
13. Read the pressure gauge and note the pressure.

The difference between the gauge readings in Steps 11 and 13 is the resistance to flow produced by the bacteria filter. If the resistance reading is more than 4 cmH_2O, the filter should be discarded.

NOTE

If any alarms are activated during the filter checkout procedure, silence the alarms with the ALARM SILENCE button.

VENTILATOR INLET FILTERS

There may be two (2) ventilator inlet filters on the BEAR® 33 Volume Ventilator. The GAS INLET filter is located behind the GAS INLET panel door located on the lower right front corner of the ventilator. Older BEAR® 33 Volume Ventilators were equipped with a case vent filter. The case vent filter will be located on the lower left side of the ventilator.

CASE VENT FILTER REPLACEMENT

The CASE VENT filter (if present) is a special filter housing. To remove the filter, the housing must be removed. Remove the two (2) screws on the bottom of the ventilator which hold the CASE VENT filter housing in place. The housing will remove by pulling down. Push the filter out of the housing and clean, if necessary.

Replace the ventilator filter into the CASE VENT housing. Screw the housing back into place.

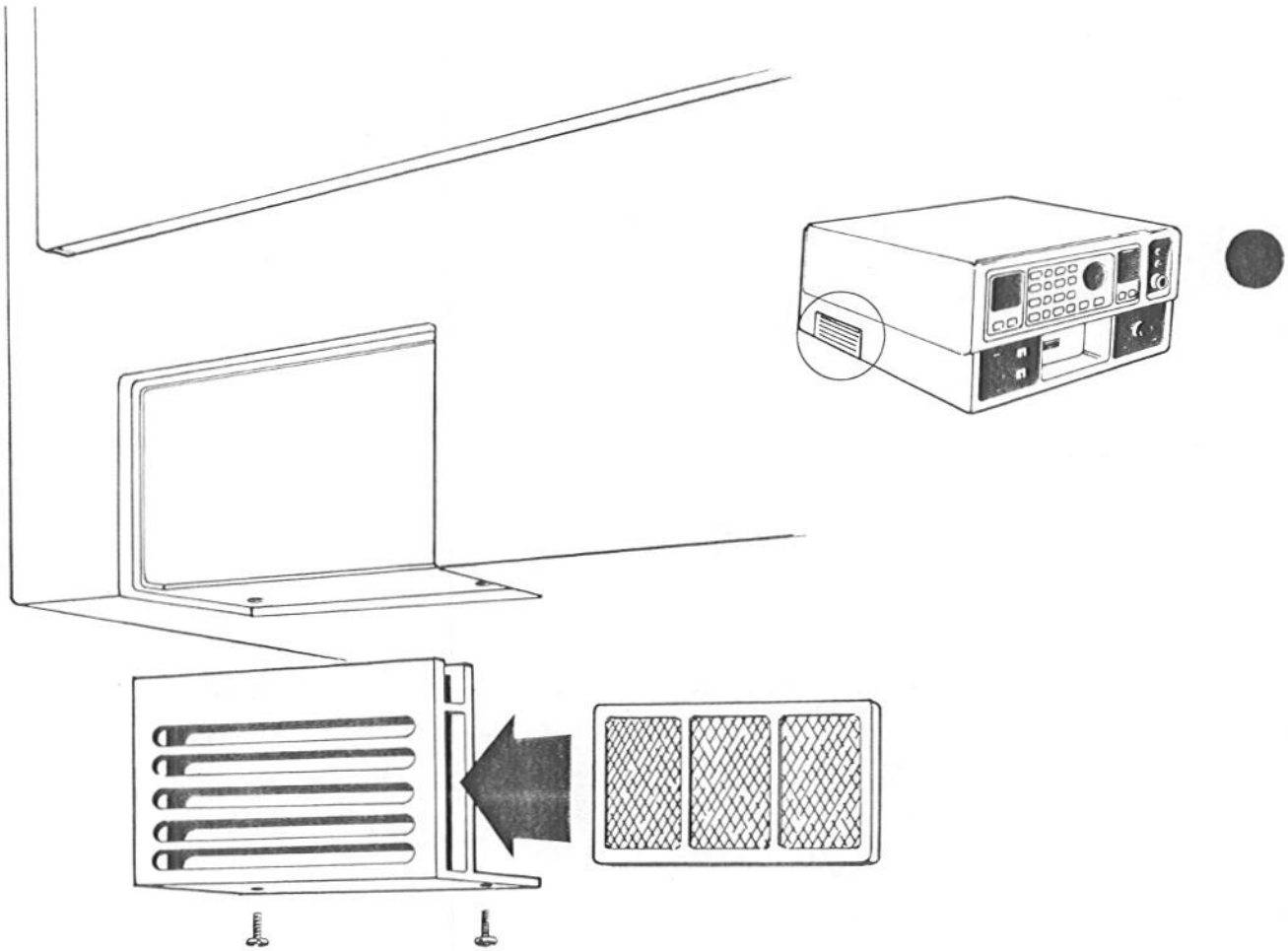


ILLUSTRATION OF
BEAR® 33 VOLUME VENTILATOR REPLACEMENT OF CASE VENT FILTER

Figure 28

GAS INLET FILTER REPLACEMENT

The GAS INLET filter is located on the lower right front corner of the ventilator behind a GAS INLET panel door. To remove the filter, the panel door must be removed. Loosen the ¼″ turn fastener holding the GAS INLET panel door in place. Pull the panel door off and remove the filter located just behind the door. Clean the filter, if necessary.

Replace the filter behind the door and screw the GAS INLET panel door back into place.

NOTE

The GAS INLET filter and the CASE VENT filter are both ventilator inlet filters. Replacement filters are packaged in sets of four (51000-08122).

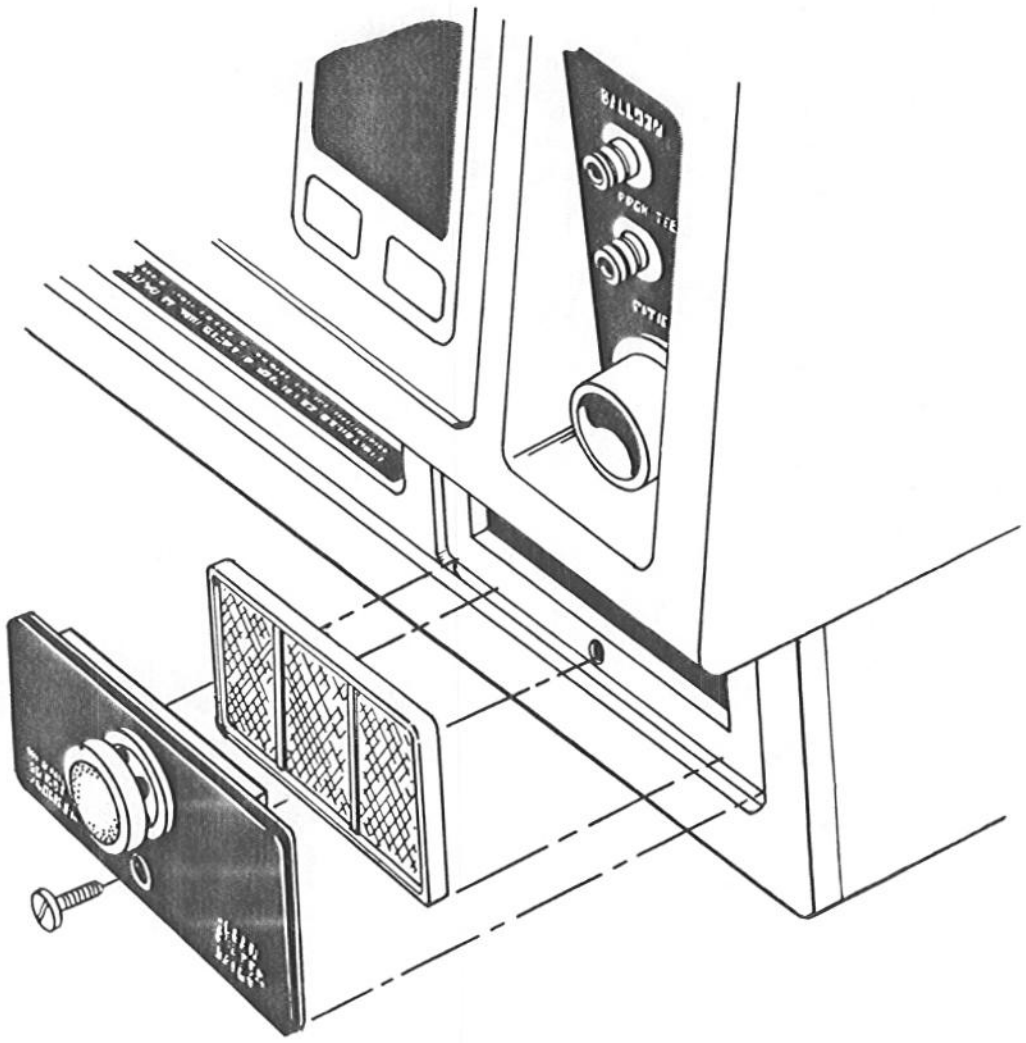


ILLUSTRATION OF
BEAR® 33 VOLUME VENTILATOR REPLACEMENT OF GAS INLET FILTER

Figure 29

DAILY

1. Run TEST.
2. Check the LOW PRESSURE, HIGH PRESSURE, APNEA and POWER CHANGE alarms.
3. **VENTILATOR INLET FILTERS** — These filters remove foreign material from the air drawn into the ventilator housing. The filters should be inspected daily. If necessary, they should be removed, washed or vacuum cleaned.

CAUTION

A clogged ventilator inlet filter can cause equipment malfunction. The filter should be inspected daily and cleaned when dust buildup is visible or at least every 500 hours of operation.

MONTHLY

VENTILATOR — An Operational Verification Procedure (OVP) should be performed a minimum of once per month. Verification may be done by a qualified operator or a Bear Trained Service Technician.

If the ventilator has not been used for a 30-day period, run the machine for 2 to 6 hours on 120 volt AC power. This is needed to keep bearings lubricated. It is recommended that the unit be plugged in, in order to maintain the internal batteries in a charged condition, and to be sure that the ventilator is ready for use when needed.

EVERY 7,000 MACHINE HOURS

PREVENTIVE MAINTENANCE — Should be completed a minimum of once every 7,000 hours of use or one year whichever comes first. Maintenance should be performed by a Bear Authorized Service Technician.

EVERY 20,000 MACHINE HOURS

OVERHAUL — The overhaul is required at a minimum of once every 20,000 machine hours. The overhaul will be performed by a Bear Service Technician at a Bear Service Center.

For more information on the Preventative Maintenance and Overhaul Programs, contact the Bear Service Department by calling (714) 788-2460 or (800) FON-BEAR.

INTERNAL AND EXTERNAL BATTERIES

The use of batteries to power the Bear® 33 Ventilator dramatically improves mobility. However, there are several important facts about batteries which should be considered.

INTERNAL BATTERY

The internal battery is for emergency use and brief periods of transition from one power source to another. It has a capacity to run the ventilator approximately one (1) hour, when at 100% charge, at 72°F. However, battery life is affected by ambient temperature and the amount of current the motor must draw to move the piston (at the selected rate and volume) against the resistance and compliance offered by the pulmonary system, see Figure 30.

The efficiency of the internal battery decreases as the temperature decreases and increases as the temperature increases above room temperature. Battery life can be reduced by 50% when operating at 32°F.

The Bear® 33 Ventilator's specified temperature range is between 32-120°F. However, you should not run the unit at these temperature extremes for long periods.

Batteries typically lose their charge when not used. High temperatures increase the rate of self-discharge. (Fig. 31). For this reason, always leave your backup Bear® 33 Ventilator plugged into an AC outlet to maintain the internal battery charge.

CAUTION

When the ventilator is not being used, turn the power off. However, leave the unit plugged into the wall. Failure to do this may shorten the life of the internal battery.

CAPACITY AS AFFECTED
BY TEMPERATURE
AT VARIOUS RATES OF DISCHARGE

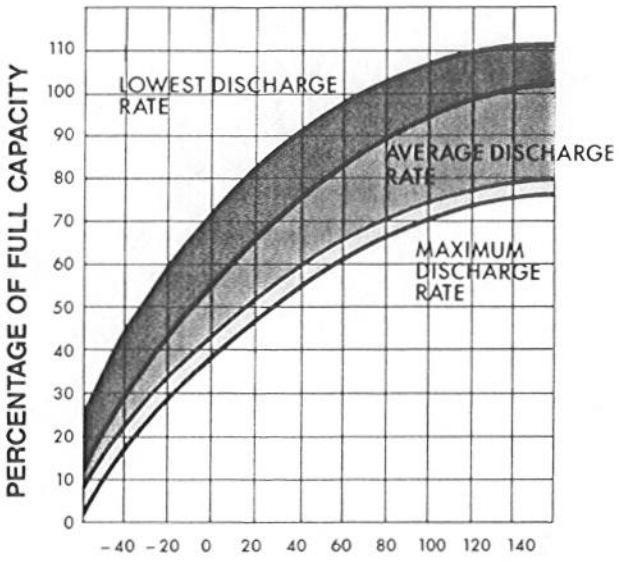


Figure 30

TYPICAL SELF
DISCHARGE CHARACTERISTICS

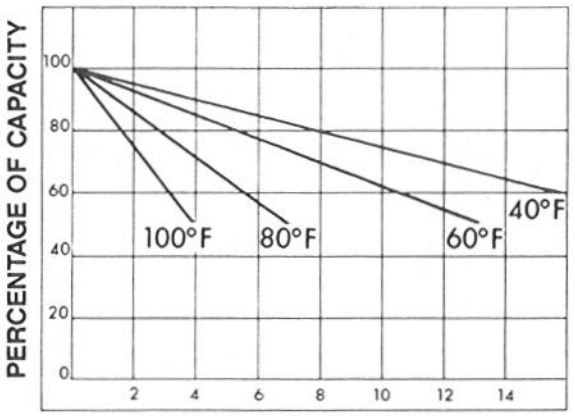


Figure 31

Figure 30, 31 is representative of discharge characteristics for batteries stored by themselves. Since the BEAR® 33 Ventilator continues to draw a minimum current in the off state, its self-discharge characteristics will be faster than indicated in Fig. 30, 31. Therefore, it is recommended the unit be plugged into AC even during storage.

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The internal battery also has important recharge characteristics over time (Fig. 32).

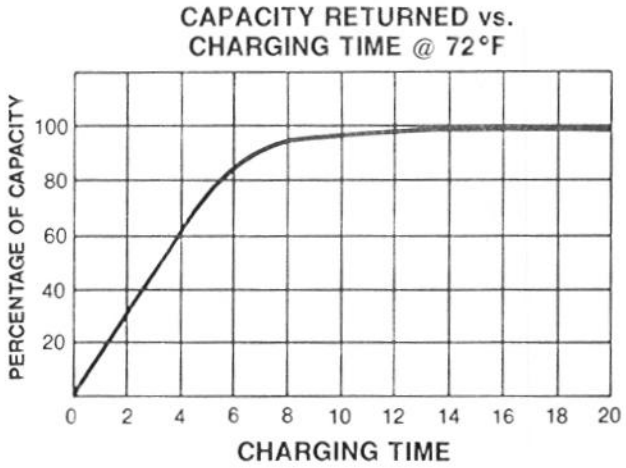

Figure 32

It can be seen that the level of charge rises rapidly betwen zero and 8 hours, to about a 95% charge and then slowly to 100% charge over the next 12 hours.

Avoid fully discharging the internal battery; however, if it is unavoidable, ensure it remains plugged into an AC outlet for at least 20 hours to return the charge to 100%.

To check the battery charge, unplug the Bear® 33 Ventilator from the AC outlet. Then read the internal battery charge indicator while the unit is running at your normal settings.

EXTERNAL BATTERY

External batteries have operating characteristics specific to their design. Generally they are affected by temperature, storage time, and have particular discharge and recharge characteristics. See the manufacturer's recommendations for proper maintenance of external batteries. The Bear® 33 Ventilator will charge the External Battery when connected if sufficient time is allowed. Generally, recharging of the external battery will require 1½ times longer than the preceding discharge. For example, 4 hours of use on a fully charged (100%) battery will require 6 hours to recharge at normal room temperature. Longer times will be required if recharge occurs at lower temperatures.

CAUTION

If the External Battery is used for 16 hours (day use) and recharged by the Bear® 33 Ventilator overnight (8 hours), the External Battery will eventually be depleted, since the 1½ times rule was not followed. It is, therefore, highly recommended that additional External Batteries be kept fully charged on a separate battery charger to meet the patient's requirements for mobility.

A SEALED DEEP CYCLE MARINE BATTERY IS RECOMMENDED FOR THE EXTERNAL BATTERY.

WARNING

Batteries represent explosive hazards. Observe all manufacturer's warnings concerning placement, handling, connection and ventilation of 12 VDC batteries.

TROUBLESHOOTING CHART

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Audible Alarm and HI PRESS Indicator flashing	1. Obstruction in patient circuit.	1. Check patient circuit for obstruction.
	2. Obstruction in tracheostomy tube.	2. Check tracheostomy tube for obstruction.
	3. Kinked tubing.	3. Unkink tubing.
	4. Blocked exhalation manifold.	4. Check exhalation manifold. Inspect for proper assembly. Clean if necessary.
	5. Inappropriate alarm setting.	5. Change alarm settings per physician direction.
	6. Change in patient compliance, resistance, TIDAL VOLUME OR PEAK FLOW.	6. Reevaluate patient condition and change TIDAL VOLUME and PEAK FLOW settings per physician direction.
Audible Alarm and LO PRESS Indicator flashing	1. Patient is disconnected.	1. Reconnect circuit to patient.
	2. Leak in patient circuit.	2. Check patient circuit for leak.
	3. Disconnected proximal pressure sensing line.	3. Check proximal pressure tee and unit for disconnect. Reconnect line.
	4. Disconnected exhalation balloon drive line.	4. Check exhalation manifold and unit for disconnect. Reconnect line.
	5. Change in patient status.	5. Reevaluate patient and change alarm settings per physician direction.
	6. Inadvertent change in LOW PRESS ALARM setting.	6. Check control setting.
	7. Patient speech or coughing.	7. Insure alarm is set at appropriate level for speech per physician direction.
Audible Alarm and LO BATT Indicator flashing	1. Less than 25% operating capacity left on the internal battery.	1. Silence the alarm for 60 seconds with the ALARM SILENCE button.
		2. Connect the unit to an external battery or plug the unit into an active AC wall source. This will cancel the audible portion of the alarm.

TROUBLESHOOTING CHART

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Flashing LO BATT Indicator (no audible alarm)	1. Less than 25% operating capacity is left on the internal battery but the ventilator is connected to an external battery or plugged into an active AC wall source.	1. The visual indicator can only be reset when the internal battery is charged above 25% operating capacity. 2. To charge the internal battery, plug the unit into an active AC wall source. 3. The CHARGING indicator will illuminate to indicate the internal battery is charging.
Audible Alarm and APNEA Indicator is flashing	1. Patient is disconnected. 2. Patient is not breathing. 3. Disconnected proximal pressure sensing line. 4. Improper ASSIST SENS setting.	1. Reconnect circuit to patient. 2. Check patient. 3. Check proximal pressure tee and unit for disconnect. Reconnect line. 4. Check the ASSIST SENS setting and reset if necessary.
Audible Alarm and VENT INOP Indicator flashing, Error Code E01 to E13 displayed in Tidal Volume window	1. Ventilator malfunction. 2. Clogged GAS INLET filter or CASE VENT filter.	1. Remove ventilator from patient, note error code, and refer unit to an authorized service technician. 2. Check ventilator GAS INLET filter for occlusion. Clean if necessary.
Audible Alarm and POWER CHANGE Indicator flashing	1. Ventilator power source has changed to a lower priority power source. 2. AC power lost at the wall outlet.	1. Check front panel to determine power source. Silence the alarm with VISUAL RESET button. 2a. Check AC circuit breaker on the lower left corner on the front of the unit. Reset the circuit breaker. Push VISUAL RESET. b. Check circuit breakers and fuses in the house. c. Check the wall receptacle.

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Audible Alarm and POWER CHANGE Indicator flashing (Cont'd)	3. Low or disconnected external battery.	3a. Check battery cable connection to battery and ventilator. b. Check fuse on the battery cable. c. Check EXT BATT meter for charge status. d. Connect to WALL AC power or new external battery.
Flashing POWER CHANGE Indicator (no audible alarm)	1. Brief power loss.	1. Cancel visual with VISUAL RESET button.
Audible Alarm and flashing control LCD displays in rotation	1. Default. 2. Default reoccurs.	1a. Depress UNLOCK button. b. Turn ventilator OFF. c. Turn ventilator ON. d. Reset control parameters. 2. Remove ventilator from patient and refer unit to an authorized service technician.
Continuous Audible Alarm. No displays or indicators illuminated	1. Complete power loss.	1a. Check circuit breaker. Depress if button is pushed out. b. Remove ventilator from patient and refer unit to an authorized service technician.
INT BATT Indicator illuminates when the external battery is connected	1. Low external battery. 2. Improper battery cable connection. 3. Blown fuse in the external battery cable.	1. Check EXT BATT charge status. 2. Check battery cable. 3. Replace fuse.
TEST does not perform	1. Test performed immediately after power ON — unit performing check sum. 2. Ventilator malfunction.	1. Wait 5 seconds and repeat. 2. Remove ventilator from patient and refer unit to an authorized service technician.

TROUBLESHOOTING CHART

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
WALL AC indicator does not illuminate when unit connected to 110 VAC	1. AC circuit breaker is open. 2. AC power cord is not properly connected. 3. No AC wall power.	1. Reset circuit breaker. 2. Check plug. 3a. Check house fuses and circuit breakers. b. Check the wall receptacle.
Control settings frozen and cannot be set	1. Panel is not unlocked.	1a. Depress UNLOCK button. Set parameters. 1b. If still unable to access the settings, refer unit to an authorized service technician.
Ventilator autocycles	1. ASSIST SENS set above baseline.	1. Reset ASSIST SENS level per physician direction.
Unit does not deliver adequate patient pressure	1. TIDAL VOLUME set below patient tidal volume. 2. Leak in patient circuit.	1. Reset TIDAL VOLUME per physician direction. 2. Check patient circuit.
Patient unable to trigger an assisted breath	1. ASSIST SENS set too low. 2. No one-way valve on patient manifold. 3. Leak in patient circuit.	1. Reevaluate patient and reset ASSIST SENS per physician direction. 2. Add one-way valve to patient manifold. 3. Check patient circuit for proper assembly.
Erratic jerking of proximal airway pressure gauge needle	1. Water in patient circuit.	1. Check for water in circuit and empty the circuit.

ORDERING INFORMATION

See chart below for items included with the BEAR® 33 Volume Ventilator, Patient Circuit Kit, Main Flow Bacteria Filter Kit and Training Package. Parts and accessories may be ordered individually or packaged as listed.

Description	Part Number	Suggested Accessories
BEAR® 33 Volume Ventilator (120 VAC, 60 Hz) with Patient Circuit Kit, P/N 51000-08020	50000-00833	Humidifier — Adult or Infant Humidifier Table Mount Bracket Additional Patient Circuit Kit Main Flow Bacteria Filter Kit

ACCESSORIES

Part Number	Description	Part Number	Description
51000-08143	Accumulator, Oxygen	50000-00460	Humidifier, Infant
51000-08131	Alarm, Remote	51000-08141	Pole Mount, Ventilator (Includes wheel base)
51000-08124	Bracket, Humidifier, Table Mount	51000-08108	Tube, Oxygen Accumulator 25.4 mm I.D.-22 mm I.D. 9 inches
51000-08127	Cable, External Battery		
51000-08129	Cable, External Battery Automobile Lighter Adapter	51000-08118	Valve, One-way
51000-03390	Cover/Jar Assembly with Heater, Adult	51000-08163	Gas inlet adapter
51000-02300	Cover/Jar Assembly with Heater, Infant	50000-03106	Exhalation Balloon assembly
50000-00420	Humidifier, Adult	51000-08230	Exhalation Balloon Seal
		51000-08117	Valve-PEEP Adjustable 0-20 cmH_2O

ITEMS INCLUDED

Part Number	Description	50000-00833 BEAR® 33 Volume Ventilator Complete	51000-08020 Patient Circuit Kit	50000-10134 Training Package	51000-08104 Main Flow Bacteria Filter Kit
51000-08106	Clip, Tubing (10 pack)	1	1		
51000-01054	Filter, Main Flow Bacteria				1
51000-08122	Filter, Ventilator Inlet (4 pack)	1†			
51000-08114	Flextube, Trache-ostomy, 15 mm, I.D.-22 mm I.D. 4''	1	1		
51000-08115	Manifold, Patient	1†	1		
50000-10133	Manual, Clinical Instruction	1†		1	
50000-10132	Manual, Patient Instruction with Cassette	1		1	
50000-10131	Manual, Ventilator Training	1		1	
51000-08116	Tee, Proximal Pressure	1†	1		
51000-08113	Tubing, Bacteria Filter 9 (2 pack)				1
51000-08112	Tubing, Humidifier, 18	1	1		
51000-08109	Tubing, Patient, 5′	1	1		
50000-03038	Tubing, PVC, 1/8″ I.D. 8′	1*	1*		
50000-03036	Tubing, PVC, 3/16″ I.D. 8′	1*	1*		

*Consult Price Book for quantities when reordering.

†Accessories included with the BEAR® 33 Volume Ventilator Basic (50000-00834).

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